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IN THE

Supreme Court of the United States

OCTOBER TERM, 1996

COMMITTEE OF DENTAL AMALGAM ALLOY MANUFACTURERS AND DISTRIBUTORS AND DENTSPLY INTERNATIONAL INC.,

Petitioners,

v.

RICHARD A. BECKER, DIRECTOR OF THE OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT, DANIEL E. LUNGREN, ATTORNEY GENERAL OF THE STATE OF CALIFORNIA, AND ENVIRONMENTAL LAW FOUNDATION,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

Of Counsel:
THOMAS F. FISE
AMERICAN DENTAL TRADE ASSOCIATION
4900 B. South 31st Street
Arlington, Va. 22206-1656

STANLEY W. LANDFAIR
DANIEL G. JARCHO*
MCKENNA & CUNEO, L.L.P.
1900 K Street, N.W.
Washington, D.C. 20006
(202) 496-7500

Counsel for Petitioners

**Counsel of Record*

PRESS OF BYRON S. ADAMS ✦ WASHINGTON, D.C. ✦ 1-800-347-8208

69 pp

QUESTION PRESENTED

Whether the Federal Food, Drug, and Cosmetic Act ("FDCA") preempts a California statute that requires reproductive toxicity warnings for a medical device, even though the United States Food and Drug Administration has considered and rejected such warnings and imposed different warning requirements on the same device under the FDCA.

RULE 29.6 STATEMENT

Petitioner Dentsply International Inc. has the following nonwholly owned subsidiaries: Stomatologia Dentsply (Stomadent) (Russia); Ceramed, LCC; Industria, e Commercia Ltda. (Brazil).

The Rule 29.6 statement concerning petitioner Committee of Dental Amalgam Alloy Manufacturers and Distributors has been filed under seal.

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COMMITTEE OF DENTAL AMALGAM ALLOY MANUFACTURERS AND DISTRIBUTORS AND DENTSPLY INTERNATIONAL INC.,
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RICHARD A. BECKER, DIRECTOR OF THE OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT, DANIEL E. LUNGREN, ATTORNEY GENERAL OF THE STATE OF CALIFORNIA, AND ENVIRONMENTAL LAW FOUNDATION,
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On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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PETITION FOR WRIT OF CERTIORARI

Petitioners Committee of Dental Amalgam Manufacturers and Distributors and Dentsply International Inc. ("Committee") hereby petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case. The Ninth Circuit held that a California state statute that requires reproductive toxicity warnings for a medical device is not preempted, even though the United States Food and Drug Administration ("FDA") has considered and rejected such warnings and imposed different warning requirements on the same device under the FDCA. The Ninth Circuit's ruling permits California to require warnings that the United States Department of Health and Human Services has indicated violate federal law.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a) is reported at 92 F.3d 807 (9th Cir. 1996). The opinion of the United States District Court for the Southern District of California granting summary judgment for petitioners (Pet. App. 1c) is reported at 871 F. Supp. 1278 (S.D. Cal. 1994).

JURISDICTION

The court of appeals entered judgment on August 5, 1996. Pet. App. 1a. This Court has jurisdiction under 28 U.S.C. 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The appendix (Pet. App. 1d) sets forth verbatim the following statutory and regulatory provisions: 21 U.S.C. 360k and 21 C.F.R. 808.1(d) (excerpt).

STATEMENT OF THE CASE

The Ninth Circuit held that the FDCA's express preemption provision does not bar a California statutory warning requirement for a medical device, even though the FDA has considered and rejected such warnings and imposed different warning requirements under the FDCA. The Ninth Circuit's construction of the FDCA preemption provision conflicts fundamentally with the principles underlying decisions in seven other circuits by concluding that the FDCA does not preempt "general" state laws that apply to medical devices as well as other products. In addition, the decision below conflicts with the premises of decisions in four other circuits by holding that federal requirements do not preempt state law if they regulate more than one type of medical device. This petition asks this Court to review a question of profound significance to all manufacturers and users of medical devices—whether a state legislature may impose requirements

on medical devices that the FDA has considered and rejected as unfounded.

A. Federal Law Background

1. The Statutory Structure

In 1976, Congress passed the Medical Device Amendments ("MDA") to the FDCA, establishing comprehensive federal regulation of medical devices for the first time. Under the MDA, the FDA has extensive authority to ensure the safety and effectiveness of medical devices. Congress enacted the MDA as "a balanced regulatory proposal" intended to assure both that the public health is protected and that "innovations in medical device technology are not stifled by unnecessary restrictions." H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976). Through the MDA, Congress sought to encourage research and development of "sophisticated, critically important medical devices," as well as to give the FDA the necessary authority to ensure the public health and safety. S. Rep. No. 33, 94th Cong., 2d Sess. 2 (1975).

Consistent with the congressional intent to promote innovation by eliminating unnecessary regulation, the MDA include the following express preemption provision:

> Except as provided in subsection (b) * * * no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. 360k(a).[1] The House committee report for the MDA describes the preemption provision as a "general prohibition on non-Federal regulation," making clear that Congress intended broad preemption of state law under section 360k. H.R. Rep. No. 853, at 45.

The federal requirements giving rise to preemption under section 360k are extensive. Under the FDCA, the FDA regulates medical devices in the context of a classification scheme that distinguishes among devices based upon the concerns they raise about safety and effectiveness. The FDA assigns medical devices intended for human use to one of three classes, effectuating its classification decision through notice and comment rulemaking procedures. See 21 U.S.C. 360c(b)(1); 21 C.F.R. 860.84. Class I devices, which the FDA believes pose no unreasonable health risks, are subject to general controls designed to ensure that labeling is accurate, that the product is safe when used as directed, and that it has been manufactured under proper quality assurance procedures. See 21 U.S.C. 360c(a)(1)(A). Class II devices are those for which special controls may be necessary to assure safety and effectiveness. *Id.* § 360c(a)(1)(B). These special controls may include performance standards, postmarket surveillance, patient registries, and other requirements the FDA deems appropriate. *Id.* In general, Class III devices are those represented to be life-sustaining or life-supporting, or those presenting a potentially unreasonable risk of illness or injury. *Id.* § 360c(a)(1)(C).

In general, the regulatory structure established by the MDA requires the FDA to review and authorize marketing of new medical devices under one of two clearance processes. First, the FDA authorizes marketing of some Class III de-

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[1] The exception in subsection (b) permits states to apply for an exemption from the preemption imposed by subsection (a). *Id.* § 360k(b).

vices through the premarket approval process. To obtain this authorization, the manufacturer submits a premarket approval application ("PMA") containing significant information about the device for FDA review. If clinical data and other information in the PMA demonstrate that the device's safety and effectiveness are reasonably assured, the FDA approves marketing. See *id.* § 360e(c), (d).

Second, all Class II devices and some devices in Classes I and III are subject to FDA premarket clearance through the "510(k)" process. This process is established by, and named after, section 510(k) of the FDCA, 21 U.S.C. 360(k). Through the 510(k) process, the FDA determines whether devices are substantially equivalent to "preamendment" devices marketed prior to the adoption of the MDA in 1976. The 510(k) substantial equivalence determination is designed to ensure that new devices are as safe and effective as preamendment devices. See H.R. Rep. No. 853, at 36-37 (explaining that substantial equivalence determination involves safety and effectiveness determination).

The MDA define the term "device" broadly, giving the FDA regulatory jurisdiction over a wide spectrum of medical products. Although some devices depend on advanced technology for their operation, others are relatively simple materials that fit the statutory definition of a device because they are implanted into the body and intended for use in the "cure, mitigation, treatment, or prevention of disease, in man or other animals." 21 U.S.C. 321(h)(2). The medical device implicated by the present case is dental mercury—a material used to make silver fillings for the treatment of tooth decay. Dental mercury typically is combined with a second device (amalgam alloy) in the dentist's office to form a third device (dental amalgam) which is used as a filling material for dental cavities. The FDA has assigned dental mercury to Class I and subjected it to premarket clearance through the 510(k) process. Cf. 21 U.S.C. 360c(d)(2)(A); 21 C.F.R. 872.3700.

2. Labeling Requirements

The FDCA establishes five major categories of federal requirements that may govern the labeling of medical devices.[2] First, devices such as dental mercury, which fit the FDA's definition of a prescription device, must comply with the FDA's prescription device labeling regulation.[3] The regulation requires that the labeling must disclose information concerning use of the prescription device and warnings regarding relevant hazards, contraindications and side effects. 21 C.F.R. 801.109(c).

Second, under the FDCA's "general controls" provisions, a device is "misbranded" if the warnings in its labeling are not adequate such that the device may be dangerous to health or if use in accordance with the labeling renders it dangerous to health. 21 U.S.C. 352(f)(2), 352(j). A device also is misbranded if its labeling is "false or misleading." *Id.* §§ 352(a), 321(n).

Third, manufacturers of devices such as dental mercury, which enter the marketplace through the 510(k) process, must submit proposed labeling for agency review to obtain premarket clearance. 21 C.F.R. 807.87(e). After marketing begins, the 510(k) requirements also bar manufacturers from

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[2] The FDCA defines "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. 321(m). Under the FDCA, "labeling" includes a broad variety of product literature (including technical manuals explaining product use and promotional materials), even if they do not physically accompany distribution of the device. See *Kordel* v. *United States*, 335 U.S. 345, 349 (1948).

[3] A prescription device is one which, "because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device." 21 C.F.R. 801.109.

changing labeling warnings in a manner that could affect safety or effectiveness of the device significantly unless the FDA clears the labeling changes through another 510(k) review. See 21 C.F.R. 807.81(a)(3)(i).

Fourth, the FDA has substantial authority to require additional labeling warnings once marketing begins. Under 21 C.F.R. 895.25, the FDA may require manufacturers to change a device's labeling to contain statements, notices, or warnings if the device presents unreasonable public health risks. 21 C.F.R. 895.25(a), (b).

Finally, under its general rulemaking authority, the FDA may promulgate regulations requiring specific labeling warnings for a particular type of device. See, e.g., 21 U.S.C. 371(a) ("authority to promulgate regulations for the efficient enforcement of [the FDCA]"); 21 C.F.R. 801.420 (hearing aid labeling requirements); *id.* § 801.430 (tampon labeling requirements). The FDA may promulgate such regulations on its own initiative or in response to a petition filed by an interested party. See 21 C.F.R. 10.25 (a), (b). When considering whether to issue such regulations, the FDA typically consults with a panel of outside experts established under the FDCA to advise the Agency about matters requiring particular scientific expertise. See 21 U.S.C. § 360c(b) (authority for establishing expert panels). The Agency has assembled the Dental Device Panel (composed of national experts in the field of dentistry) to perform this function with respect to devices such as dental mercury.

If the FDA considers promulgating a labeling regulation or taking other action to impose significant warning requirements on a particular device but ultimately determines that such requirements are not justified, the FDCA may prohibit the manufacturer from adding the warnings voluntarily. The 510(k) requirements prohibit the addition of labeling warnings that could significantly affect the safety or effectiveness of the device unless the FDA clears them as legitimate. See

21 C.F.R. 807.81(a)(3)(i). This prohibition on changes in labeling applies regardless of whether the manufacturer believes that they would decrease or increase device safety or effectiveness.[4] In addition, if the FDA determines that there is no legitimate scientific basis for the warnings, the general controls provisions of the FDCA barring misleading labeling would prevent the manufacturer from adding the warnings. See 21 U.S.C. 352(a), 321(n).

B. This Litigation

On September 21, 1993, petitioners filed this action for declaratory and injunctive relief in the Southern District of California, Pet. App. 4a, arguing that the FDCA preempts reproductive toxicity warning requirements for dental mercury imposed by California's Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986, Cal. Health & Safety Code 25249.5-13.[5] Proposition 65 imposes warning requirements on a wide variety of consumer products, including some medical devices regulated by the FDA. With certain exceptions, Proposition 65 prohibits any person from "knowingly and intentionally expos[ing] any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving *clear and reasonable warning* to such individual." *Id.* § 25249.6 (emphasis added). California has designated mercury as a reproductive toxin "known to the state," thereby imposing the statutory warning requirements on dental mercury and other products containing mercury.

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[4] See, e.g., 42 Fed. Reg. 42,520, 42,522 (Aug. 23, 1977) (preamble to 510(k) regulation).

[5] Jurisdiction in the district court was based on the federal question statute, 28 U.S.C. 1331. Pet. App. 2a.

Proposition 65 does not define the terms "clear and reasonable" warning. Instead, it leaves the adequacy of warnings to be determined on a case-by-case basis through lawsuits for civil penalties and injunctive relief under the statute. Proposition 65 vests primary enforcement authority in the Attorney General and district attorneys, but allows private parties (commonly referred to as "bounty hunters") to sue "in the public interest" if the State does not "commence[]" and "diligently prosecut[e]" a suit against an alleged violator within sixty days after receiving notice of the bounty hunter's intent to sue. *Id.* § 25249.7(d).

Proposition 65 gives private parties a significant pecuniary incentive to "enforce" the statute and impose new warning requirements through the litigation process. A bounty hunter who prevails is entitled to one-fourth of any civil penalty imposed, *id.* § 25192, and receives reimbursement of its attorneys fees and costs as long as it achieves a result that is in "the public interest." Cal. Code Civ. Proc. § 1021.5 (West Supp. 1996).

Petitioners, who manufacture and distribute dental mercury in interstate commerce, brought this suit to protect themselves from bounty hunter suits initiated by respondent Environmental Law Foundation ("ELF"). Proceeding under the bounty hunter provision against one small dental mercury distributor, ELF previously had forced a settlement that imposed a series of new warning requirements and significant civil penalties. See p. 22, *infra*. ELF also had issued notices of its intent to sue a number of additional manufacturers, who brought this protective suit in the name of the Committee. In the district court, petitioners argued that federal labeling requirements preempt Proposition 65 warning requirements for dental mercury, emphasizing that the FDA has considered and formally rejected toxicity warnings as unfounded. Petitioners also argued that the Proposition 65

warning requirements for dental mercury violate the Commerce Clause of the U.S. Constitution.

The district court first considered the types of federal requirements that have preemptive effect under the FDCA. The court deferred to the following FDA regulation, which interprets the scope of the FDCA preemption provision (Pet. App. 9c & n.6):

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. 808.1(d). The court concluded that under the regulation, "[a] 'specific requirement' may apply to numerous medical devices and still be preemptive." Pet. App. 12c. The court also held that the regulation "does not state that the [FDCA] preempts state law only when it contains a requirement specifically applicable to one specific device." *Ibid.*

The district court then analyzed the federal requirements applicable to dental mercury. The court held that the prescription device labeling regulation, 21 C.F.R. 801.109, is a specific requirement with preemptive effect. Pet. App. 11c-12c. The court also concluded that there was "no genuine issue of material fact that the FDA has considered, and rejected, imposing reproductive toxicity warning requirements for dental amalgam." Pet. App. 6c.[6] The court held that the

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[6] Dental amalgam is created in the dentist's office from amalgam alloy and dental mercury. See p. 5, *supra*. Both the district court and the Ninth Circuit used the terms "dental mercury" and "dental amalgam" inter-

(Footnote cont'd on next page)

FDA's decision to reject such warnings had preemptive effect.

The district court then turned to the FDA regulation's discussion of the state law requirements that are subject to preemption. According to that regulation, section 360k does not preempt certain state requirements of "general applicability":

> Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices * * * or to unfair trade practices in which the requirements are not limited to devices.

21 C.F.R. 808.1(d)(1). The district court held that this language does not exclude Proposition 65 from the scope of the FDCA preemption provision. Pet. App. 13c.

The district court then concluded that the Proposition 65 warning requirements are "different from, or in addition to," the applicable federal requirements, *ibid.*, and granted summary judgment for petitioners on the preemption issue, Pet. App. 15c. The district court also denied summary judgment on the Commerce Clause issue because the facts were disputed, *ibid.*, and later concluded that the Commerce Clause claim was moot, Pet. App. 1b.

C. The Court of Appeals Opinion

The Ninth Circuit reversed on the preemption issue. The court premised its ruling on its reading of *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240 (1996) (which construed the scope of the FDCA preemption provision in the context of a product

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(Footnote cont'd from previous page.)

changeably, even though the state and federal requirements at issue relate primarily to dental mercury.

liability case), and the FDA's interpretive regulation, 21 C.F.R. 808.1(d). Pet. App. 10a-12a.

The court of appeals held that the Proposition 65 warning requirements are not state "requirements" within the meaning of the FDCA preemption provision. Pet. App. 12a. The Ninth Circuit concluded that in *Lohr*, this Court had "specifically approved" the language of 21 C.F.R. 808.1(d)(1) excluding requirements of "general applicability" from the scope of the preemption provision. Pet. App. 10a. The court of appeals then reasoned that the Proposition 65 warning requirements are requirements of general applicability that are preserved from preemption. Pet. App. 11a-12a.

The Ninth Circuit also held that the federal labeling requirements applicable to dental amalgam are too general to be preemptive under section 360k. The court of appeals again relied on its reading of *Lohr* and of the language in 21 C.F.R. 808.1(d) stating that only "specific" federal requirements have preemptive effect. The court of appeals concluded that to preempt state law, federal requirements must be so specific that they are uniquely applicable to a particular device. Because the federal labeling requirements at issue apply to numerous devices, the Ninth Circuit concluded that Proposition 65 is not preempted. See Pet. App. 9a-11a; pp. 18-21, *infra*.

The court of appeals also held that the FDA's consideration and rejection of reproductive toxicity warnings for dental amalgam was "inaction" by the FDA that does not preempt state law. Pet. App. 12a-13a. In denying preemption, the Ninth Circuit reasoned that the statutory language requires "a positive enactment from the FDA before preemption can be triggered." Pet. App. 12a. The Ninth Circuit's holding therefore preserved state warning requirements from preemption even though the FDA has considered and rejected the same warnings under the FDCA.

REASONS FOR GRANTING THE WRIT

I. THE COURT OF APPEALS DECISION ESTABLISHES PREEMPTION STANDARDS THAT CONFLICT WITH THE STANDARDS IN OTHER CIRCUITS

The Ninth Circuit's decision confirms a substantial conflict in principle among the circuits concerning the scope of federal preemption under the FDCA. The court of appeals decision conflicts with the premises of decisions by seven other circuits regarding the types of state requirements that are subject to preemption. The decision also conflicts with the principles underlying decisions by four other circuits regarding the types of federal requirements that have preemptive effect. In addition, this Court's construction of the FDCA preemption provision last term in *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240 (1996), does not resolve the conflicts.

A. The Conflict Regarding State Requirements Subject to Preemption

One major premise of the Ninth Circuit's holding is that Proposition 65 does not impose a state requirement subject to preemption, because it is "a state law of general applicability which was *not* enacted 'with respect to' medical devices." Pet. App. 11a. The Ninth Circuit concluded that under *Lohr* and the FDA's interpretive regulation (21 C.F.R. 808.1(d)(1)), preemption does not extend to Proposition 65, because it "applies to *all* products and services that pose a health risk to the public" and "is not directed at any product or industry." *Ibid.*

The Ninth Circuit's holding cannot be reconciled with the premises of a recent Third Circuit decision, *Michael* v. *Shiley, Inc.*, 46 F.3d 1316 (3d Cir.), cert. denied, 116 S. Ct. 67 (1995). In *Michael*, the Third Circuit held that state common law requirements are subject to preemption under Section 360k, even though they govern numerous products in

addition to devices. In direct conflict with the principles underlying the Ninth Circuit's ruling, the Third Circuit held that "the statutory language of § 360k" preempts common law claims for breach of implied warranty "[d]espite the reference in 21 C.F.R. 808.1(d)(1) to laws of general applicability." 46 F.3d at 1323 n.4.[7] *Michael* followed an earlier Third Circuit case, *Gile* v. *Optical Radiation Corp.*, 22 F.3d 540, 543 n.2 (3d Cir.), cert. denied, 115 S. Ct. 429 (1994), which similarly held that 21 C.F.R. 808.1(d) does not exclude common law claims from preemption under section 360k.

The Ninth Circuit's holding also conflicts with the premises of similar decisions in product liability cases in the First, Second, Fifth, Seventh, Eighth and Eleventh Circuits. All of these courts have held that generally applicable state common law requirements are subject to preemption under the FDCA. *Talbott* v. *C.R. Bard, Inc.*, 63 F.3d 25, 29 (1st Cir. 1995), cert. dismissed, 116 S. Ct. 1892 (1996); *Becker* v. *Optical Radiation Corp.*, 66 F.3d 18, 20 n.2, 20-21 (2d Cir. 1995); *Stamps* v. *Collagen Corp.*, 984 F.2d 1416, 1421 (5th Cir.), cert. denied, 510 U.S. 824 (1993); *Slater* v. *Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), cert. denied, 505 U.S. 917 (1992); *Martello* v. *Ciba Vision Corp.*, 42 F.3d 1167, 1169 (8th Cir. 1994); *Duncan* v. *Iolab Corp.*, 12 F.3d

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[7] The conflict in principle cannot be resolved by distinguishing the facts of *Michael*. Although the present case involves a state statute and *Michael* was a product liability case involving state common law requirements, this Court has indicated that FDCA preemption analysis does not depend on the source of state law. In *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240 (1996), five Justices agreed that the FDCA preempts state requirements—regardless of whether they derive from common law doctrine or legislative enactment—if they are "different from, or in addition to," an applicable federal requirement. 116 S. Ct. at 2263 (opinion of O'Connor, J.); *id.* at 2259-60 (opinion of Breyer, J.).

194 (11th Cir. 1994). Because state common law requirements are neither established solely " 'with respect to' medical devices" nor "directed at any product or industry" (see Pet. App. 11a), these decisions directly conflict with the principles underlying the Ninth Circuit decision.

This conflict in principle is not likely to be resolved without action by this Court. The Ninth Circuit appears firmly committed to its errant view that the FDCA does not preempt state requirements applicable to medical devices as well as other products. The court below cited with favor the holding of an earlier Ninth Circuit case, *Kennedy* v. *Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995), cert. denied, 116 S. Ct. 2579 (1996), which also preserved state requirements from preemption because they were not established solely with respect to medical devices. Pet. App. 8a-9a. In *Kennedy*, the Ninth Circuit denied preemption of common law claims, in part because it noted that "[s]ection 808.1(d)(1) provides that the MDA does not preempt laws of general applicability" and concluded that "[s]tate common law is a law of general applicability." 67 F.3d at 1459. The holding of the court below regarding state requirements therefore reaffirmed *Kennedy*, firmly entrenching the conflict with the other circuits on this issue.[8]

In addition, this Court's decision in *Lohr* did not resolve the conflict. On the one hand, the Court held that the FDCA regulatory scheme does not necessarily preclude " 'general' state requirements from ever being pre-empted." 116 S. Ct. at 2257. In particular, a majority of five Justices confirmed that generally applicable common law claims establish state "requirements" subject to possible preemption under section

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[8] In *Kennedy*, the Ninth Circuit recognized that its holding conflicted with the Third Circuit's decisions in *Michael* and *Gile*. See 67 F.3d at 1461 n.3.

360k(a). Justice O'Connor's opinion, which was joined by Chief Justice Rehnquist and Justices Scalia and Thomas, concluded that "state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA." *Lohr*, 116 S. Ct. at 2262 (opinion of O'Connor, J.). Justice Breyer wrote a separate concurring opinion expressly agreeing with Justice O'Connor's discussion and conclusion on this point. *Id.* at 2259 (opinion of Breyer, J).[9]

On the other hand, the majority opinion authored by Justice Stevens denied preemption in part because the state common law requirements at issue were too general and "not specifically developed 'with respect to' medical devices." *Id.* at 2258. Justice Stevens' opinion concluded that "[t]hese state requirements therefore escape pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices." *Ibid.*[10] The analytical approaches taken by the different *Lohr* opinions therefore failed to clarify the extent to which requirements that apply to products in addition to medical devices may be preempted.

Furthermore, this Court did not resolve the conflict through its disposition of other FDCA preemption cases that it held for decision on certiorari petitions pending the *Lohr* ruling. Five days after it decided *Lohr*, this Court denied the

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[9] Justices Stevens, Kennedy, Souter and Ginsburg expressly reserved the question whether common law duties are *never* "requirements" under the FDCA preemption provision. *Id.* at 2258-59 (opinion of Stevens, J.).

[10] Justice Breyer joined this portion of Justice Stevens' opinion, although he also concluded separately that he is "not convinced that future incidents of MDA pre-emption of common-law claims will be 'few' or 'rare.' " 116 S. Ct. at 2262.

petition for certiorari in *Kennedy* (thereby preserving the Ninth Circuit rule that the FDCA does not preempt requirements applicable to other products in addition to medical devices). 116 S. Ct. 2579. The denial of certiorari had the effect of continuing a conflict between Ninth Circuit doctrine and decisions of numerous other circuits.

In direct conflict with the Ninth Circuit, the First, Second, Eighth and Eleventh Circuits all decided prior to *Lohr* that generally applicable common law requirements *are* subject to preemption.[11] These circuits are unlikely to change course on their own. Because *Lohr* affirmed that common law claims are subject to preemption under appropriate circumstances, and because these cases all involved federal requirements that were not at issue in *Lohr*, they are still good law following *Lohr*. Indeed, the First Circuit has confirmed, following *Lohr*, that common law claims are subject to preemption under the FDCA. *Wilson* v. *Bradlees of New England, Inc.*, 96 F.3d 552, 554, 555-56 (1st Cir. 1996). In addition, because the Supreme Court has not considered any FDCA preemption cases in these circuits following *Lohr*, the conflict with the Ninth Circuit remains unresolved.

The same day that it denied the *Kennedy* petition, this Court vacated and remanded FDCA preemption cases from the Third, Fourth, Fifth, Sixth and Seventh Circuits, which before *Lohr* had affirmed preemption of generally applicable common law requirements in direct conflict with *Kennedy*.[12]

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[11] See, e.g., *Talbott* v. *C.R. Bard, Inc.*, 63 F.3d 25; *Becker* v. *Optical Radiation Corp.*, 66 F.3d 18; *Martello* v. *Ciba Vision Corp.*, 42 F.3d 1167; *Duncan* v. *Iolab Corp.*, 12 F.3d 194.

[12] *English* v. *Mentor Corp.*, 67 F.3d 477 (3d Cir. 1995), *vacated and remanded*, 116 S. Ct. 2575 (1996); *Duvall* v. *Bristol-Myers Squibb Co.*, 65 F.3d 392 (4th Cir. 1995), *vacated and remanded*, 116 S. Ct. 2575 (1996); *Bingham* v. *Mentor Corp.*, 89 F.3d 203 (5th Cir.), *vacated and*

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It is not likely that these circuits will change course on this issue, however, given the holding in *Lohr* that common law claims are subject to preemption. In three of these circuits (the Third, Fifth and Seventh), the decisions on remand will likely be influenced by older pre-*Lohr* decisions, discussed above, that affirm preemption of generally applicable common law requirements in conflict with Ninth Circuit doctrine.[13] In any event, regardless of how the Third, Fourth, Fifth, Sixth and Seventh Circuit cases are decided on remand, they will not resolve the substantial conflict between the Ninth and the First, Second, Eighth and Eleventh Circuits described above. As a result, only further action by this Court can clarify on a nationwide basis the extent to which the FDCA preempts requirements of general applicability.

B. The Conflict Regarding Preemptive Federal Requirements

Another fundamental premise of the Ninth Circuit's decision is its holding that federal requirements must apply exclusively to one type of medical device to preempt state law. The Ninth Circuit concluded that the district court was "wrong" when it held that Proposition 65 is preempted even though there are no " 'specific' [FDA] regulations relating to dental amalgam." Pet. App. 10a-11a. In so holding, the Court of Appeals rejected the district court's conclusion that the FDCA may preempt state law even if there is no

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remanded, 116 S. Ct. 2577 (1996); *Feldt* v. *Mentor Corp.*, 61 F.3d 431 (5th Cir. 1995), *vacated and remanded*, 116 S. Ct. 2575 (1996); *Martin* v. *Telectronics Pacing Sys., Inc.*, 70 F.3d 39 (6th Cir. 1995), *vacated and remanded*, 116 S. Ct. 2576 (1996); *Mitchell* v. *Collagen Corp.*, 67 F.3d 1268 (7th Cir. 1995), *vacated and remanded*, 116 S. Ct. 2576 (1996).

[13] *Michael* v. *Shiley, Inc.*, 46 F.3d 1316; *Gile* v. *Optical Radiation Corp.*, 22 F.3d 540; *Stamps* v. *Collagen Corp.*, 984 F.2d 1416; *Slater* v. *Optical Radiation Corp.*, 961 F.2d 1330.

"requirement specifically applicable to one specific device." Pet. App. 12c.

The Ninth Circuit confirmed its analysis of federal requirements by reaffirming two of its prior decisions "narrowly construing the MDA's preemption clause." Pet. App. 8a-9a. One of these decisions is *Kennedy*, in which the court held that the FDA's PMA requirements are not sufficiently specific to be preemptive, because they apply to "*[a]ll* Class III devices" rather than to a single device type. 67 F.3d at 1459. The other decision is *Anguiano* v. *E.I. Dupont de Nemours & Co.*, 44 F.3d 806 (9th Cir. 1995), in which the court similarly premised preemption on the existence of a federal requirement "specifically addressing the device." 44 F.3d at 810.

The holding of the court below regarding preemptive federal requirements conflicts squarely with premises of decisions of four other circuits. The First, Third, Fifth and Eighth Circuits have held that the PMA requirements are preemptive "specific" requirements within the meaning of 21 C.F.R. 808.1(d), although they apply to hundreds of different device types. See *King* v. *Collagen Corp.*, 983 F.2d 1130, 1134 (1st Cir.), cert. denied, 510 U.S. 824 (1993); *Michael* v. *Shiley, Inc.*, 46 F.3d at 1324 (3d Cir.); *Stamps* v. *Collagen Corp.*, 984 F.2d at 1422 n.3, 1424 n.8 (5th Cir.); *Martello* v. *Ciba Vision Corp.*, 42 F.3d at 1169 (8th Cir.).[14] These decisions cannot be reconciled with the test applied by the court below, leaving the Ninth Circuit with a unique doctrine that drastically restricts preemption in comparison with the law of other circuits.

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[14] Almost 20 percent of the new Class III devices that enter the market each year are subject to the PMA requirements. Cf. H.R. Rep. No. 808, 101st Cong., 2d Sess. 14.

This Court's decision in *Lohr* did not resolve the conflict over the extent to which federal requirements applicable to numerous devices may be preemptive under section 360k(a). In *Lohr*, the Court did not articulate a clear-cut test for the lower courts to identify a preemptive federal requirement. On the one hand, the Court stated that it did "not believe" that the MDA preemption provision and the FDA's preemption regulation "necessarily preclude[] 'general' federal requirements from ever pre-empting state requirements." 116 S. Ct. at 2257. On the other hand, the Court held that the federal manufacturing and labeling requirements at issue in *Lohr* were too general to preempt the particular common law claims under review. *Id.* at 2257-58.[15] The Court's primary guidance for the lower courts was to state that there must be "a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement" to address the "overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." *Ibid.* By adopting a case-by-case approach, *Lohr* did little to resolve the fundamental conflict in principle between the circuits regarding the test for preemptive federal requirements.

Furthermore, the circuits do not appear likely to resolve the conflict on their own. Given its reaffirmation of prior circuit doctrine, the Ninth Circuit is unlikely to reconsider its test for preemptive federal requirements. Similarly, the First and Eighth Circuits have no reason to reconsider their conflicting test, in light of the fact that *Lohr* does not exclude

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[15] The Court did *not* hold that these federal requirements can *never* preempt state law. See *ibid.* Indeed, should this Court grant this petition, petitioners will argue, inter alia, that in the particular context of this case (including the FDA's decision not to adopt reproductive toxicity warnings for dental mercury) the federal labeling requirements at issue in *Lohr* do preempt Proposition 65.

general federal requirements from the scope of the preemption provision. See 116 S. Ct. at 2257. Furthermore, the Third and Fifth Circuits, which are considering cases remanded in the wake of *Lohr*, see pp. 17-18 & n.12, *supra*, may add fuel to—but cannot resolve—the conflict among these other circuits.

C. This Court Should Resolve the Conflict Regarding Preemption Standards

This Court should resolve the conflict among the circuits regarding the tests for state and federal requirements encompassed by the FDCA preemption provision. Currently, state legislative power over medical devices varies greatly from State to State. In the Ninth Circuit, the scope of preemption under the FDCA is extremely narrow, giving legislatures in Ninth Circuit states extensive authority to regulate medical devices. The FDA almost never regulates with requirements specific enough to meet the Ninth Circuit's test for preemptive federal requirements; there are fewer than two dozen substantive device-specific FDA regulations, and only one device-specific requirement in the FDCA. It also is unusual for States to enact consumer protection statutes that regulate medical devices but no other products, rendering the Ninth Circuit's test for state requirements extraordinarily difficult to satisfy. The Ninth Circuit's limitations on FDCA preemption therefore authorize expansive state legislative power. In contrast, legislative authority is much more limited in the States of other circuits that interpret the FDCA preemption provision more broadly.

As a result of conflicting preemption standards among the circuits, national medical device manufacturers doing business in all fifty States currently confront a confusing and disjointed pattern of regulatory requirements. The warning requirements imposed under Proposition 65 provide an apt illustration. Manufacturers that distribute dental mercury on a nationwide basis are subject to burdensome warning re-

quirements in California. One recent "bounty hunter" case brought by respondent ELF was resolved through a consent judgment that required the defendant to pay $328,000 in civil penalties and withdraw the device from commerce in California if its dentist customers failed to post warning signs in their offices encouraging patients to inquire about alternative dental restoration materials. *Environmental Law Found.* v. *Jeneric/Pentron Inc.*, No. 957039 (Cal. Super. Ct. San Francisco County Dec. 13, 1993) (stipulation for judgment). In contrast, other states in the Ninth Circuit are free to require different warnings while states outside the Ninth Circuit remain governed by federal warning requirements.

These differing requirements disrupt the rational and efficient development, production, and sale of critical medical devices, undermining the very purpose of the FDCA preemption provision. Congress enacted that provision to enhance uniformity of regulatory requirements so that the regulatory structure would not stifle technological innovations of vital importance to the public health. Until this Court resolves the disarray among the circuits regarding preemption standards, this burden on innovation will persist. This Court should grant this petition to establish a uniform rule of law necessary for an efficient and rational medical device regulatory system.

II. THIS CASE PRESENTS AN IMPORTANT FEDERAL QUESTION THAT HAS NOT BEEN, BUT SHOULD BE, SETTLED BY THIS COURT

A decision by this Court on the question presented would resolve a significant question of federalism profoundly important to the public health—whether the FDCA places regulation of medical devices in the hands of an expert federal agency or gives state legislatures relatively free reign to dictate regulatory requirements. This Court never has considered the scope of state legislative power over medical de-

vices. A decision in this case would allow this Court to resolve the tension between federal control of medical devices and control by the States, which "traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Metropolitan Life Ins. Co.* v. *Massachusetts*, 471 U.S. 742, 756 (1985) (internal quotation marks omitted).

In particular, a decision by this Court in this case would resolve the significant question whether a state legislature may impose requirements on medical devices that FDA experts have considered and affirmatively rejected as unfounded. Although this Court has explained in other contexts that intentional inaction by a federal regulator under a comprehensive regulatory scheme may preempt conflicting state law, see, e.g., *Puerto Rico Dep't of Consumer Affairs* v. *Isla Petroleum Corp.*, 485 U.S. 495, 503 (1988), it never has addressed the issue under the FDCA. By granting the petition, the Court would help define the FDA's authority to specify what is—and just as importantly, what is not—required to ensure that the public health is protected.

The FDA has long recognized that under some circumstances, inappropriate product warnings may have an adverse effect on the public health. Unfounded warnings may cause patients to discontinue valuable therapies, shift to new therapies that present greater risks, or suffer unnecessary psychological trauma. The FDCA itself expresses the importance of these concerns about inappropriate warnings, granting the FDA discretion, based on its scientific expertise, to determine whether patients should be notified of particular risks arising from medical devices, or whether "notice to such individuals would present a *greater danger* to the health of such individuals than no such notification." 21 U.S.C. 360h(a) (emphasis added).

The warning requirements that gave rise to the present case illustrate well the importance of defining the FDA's

authority to regulate through intentional inaction. According to a recent government report, one of the particular concerns raised by dental mercury warnings is the prospect that thousands of patients might respond by having existing dental fillings removed and replaced by potentially riskier and more expensive devices, at an increased cost that could exceed $12 billion per year. Public Health Service, Department of Health and Human Services, *Dental Amalgam: A Scientific Review and Recommended Public Health Service Strategy for Research, Education and Regulation* xi, 10, 17 (1993). By granting the petition, the Court would have the opportunity to define the FDA's authority to maintain control over its critical regulatory program by barring States from imposing unwarranted warning requirements.

At the same time, granting the petition would allow the Court to clarify the circumstances under which the absence of federal regulation *does* allow the States room to regulate medical devices. The Ninth Circuit noted that if the FDA's inaction on a particular subject were always sufficient to trigger preemption, manufacturers would be free to ignore state consumer protection laws during the period that the FDA is considering whether to take regulatory action. See Pet. App. 13a. If the Court grants review in this case, it could define the circumstances under which state laws can protect users of medical devices in the absence of federal regulation.

A decision in this case also could define more generally the relationship between state and federal power over the critically important medical device industry. This case provides the Court with an excellent opportunity to address this important issue of federalism, because the federal and state interests at issue are both significant; the federal statute derives from a substantial congressional concern for strong regulation of medical devices at the federal level, and the state statute arises from traditional core state concerns regarding consumer protection.

In addition, this case presents a superb opportunity to clarify the balance of power between the state and federal governments, because the particular assertion of state legislative power under Proposition 65 is extraordinary. At a minimum, Proposition 65 allows the State of California to *penalize* manufacturers and distributors for marketing a device without Proposition 65 warnings, even though federal law *authorizes* marketing the same device without such warnings. See Cal. Health & Safety Code § 25249.7(b) (penalties of $2,500 per day for each violation of Proposition 65 warning requirements). In addition, Proposition 65 allows imposition of these state penalties for federally-authorized conduct through "bounty hunter" suits by private parties, *even if the State of California declines suit. Id.* § 25249.7(d). Indeed, the current case arises in the context of a decision by the State of California not to bring suit under Proposition 65 regarding dental mercury, because it had "completed an extensive review of the literature" and determined that "there is no conclusive evidence of the reproductive toxicity of mercury." Letter from Chief Deputy Attorney General to Kerr Manufacturing Co. of Sept. 20, 1993 (C.A. Supplemental Excerpts of Record at SER 952).[16] The unusually expansive state power asserted under Proposition 65 gives the Court an

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[16] Although compelled to defend Proposition 65 in this suit, the California Attorney General would be the first to admit that Proposition 65 suits have a confounding effect on federal and state laws. In early 1996, the Attorney General sponsored a bill in the California Assembly to control suits by "bounty hunters." The bill's preamble states that actions by "irresponsible private groups" imposing warning requirements under this law have "resulted in an inaccurate perception of the requirements of the act and have resulted in businesses providing warnings * * * so as to prevent being subjected to unfounded litigation, thereby generating needless warnings that confuse the public and reduce the effectiveness of necessary warnings." A. 3160, 1995-96 Regular Sess. (Cal. introduced Feb. 23, 1996).

unusually good context for addressing the important federalism issues at stake.[17]

Finally, this case is appropriate for Supreme Court review, because Proposition 65 may *require* warnings that *violate* federal law. A recent report of the Department of Health and Human Services concluded that federal law prohibits certain warnings currently being imposed under Proposition 65:

> Advertising is considered to be labeling. If individual dentists were participating in *false advertising such as claiming that dental amalgams are toxic to humans* or causative agents for diseases, and if literature purporting [sic] these claims were on the premises of the dentist's office, *FDA would have the authority to take legal action* against that dentist.

Dental Amalgam: A Scientific Review at VI-5 (emphasis added).[18] The stark contrast between state and federal requirements in this case presents the best opportunity this Court has yet had to define the complex relationship between federal and state regulatory power over critically important medical devices.

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[17] The national significance of the federalism issues posed by Proposition 65 is confirmed by a recent *Federal Register* notice. The Occupational Safety and Health Administration presently is considering whether to preempt the application of Proposition 65 and its "bounty hunter" provisions to products distributed for use in work places. See 61 Fed. Reg. 48,443 (Sept. 13, 1996).

[18] Respondent ELF has demanded and obtained such warnings under the authority of Proposition 65 and is currently threatening new litigation against petitioners on the same issue. See p. 22, *supra*.

CONCLUSION

This Court should grant the petition for certiorari.

Respectfully submitted,

Of Counsel
THOMAS F. FISE
AMERICAN DENTAL TRADE ASSOCIATION
4900 B. South 31st Street
Arlington, Virginia 22206-1656

STANLEY W. LANDFAIR
DANIEL G. JARCHO*
MCKENNA & CUNEO, L.L.P.
1900 K Street, N.W.
Washington, D.C. 20006
(202) 496-7500

Counsel for Petitioners

**Counsel of Record*

November 4, 1996

[reported at 92 F.3d 807]

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

COMMITTEE OF DENTAL AMALGAM MANUFACTURERS AND DISTRIBUTORS; DENTSPLY INTERNATIONAL, INC.

Plaintiffs-Appellees,

v.

JAMES STRATTON, Dr., Interim Director of the Office of Environmental Health Hazard Assessment; DANIEL E. LUNGREN, Attorney General of the State of California,

Defendants-Appellants,

and

ENVIRONMENTAL LAW FOUNDATION,

Intervenor-Appellant.

Nos. 94-56508, 94-56512
D.C. No. CV-93-01439-RMB

OPINION

Appeal from the United States District Court for the Southern District of California

Rudi M. Brewster, District Judge, Presiding

Argued and Submitted March 5, 1996—Pasadena, California

Filed Aug. 5, 1996.

Before: Pregerson, Thomas G. Nelson, Circuit Judges, and Eugene F. Lynch, District Judge.*

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* The Honorable Eugene F. Lynch, United States District Judge for the Northern District of California, sitting by designation.

COUNSEL

Susan S. Fiering, Deputy Attorney General, Oakland, California, for the defendants-appellants.

James Wheaton, Environmental Law Foundation, Oakland, California, for the intervenor-appellant.

Stanley W. Landfair, McKenna & Cuneo, San Diego, California, for the plaintiffs-appellees.

OPINION

PREGERSON, Circuit Judge:

The defendants, Dr. James Stratton, Acting Director of the California Office of Health Hazard Assessment, and Dan Lungren, the Attorney General of the State of California (collectively the "State"), and the intervening party, Environmental Law Foundation ("ELF"), appeal the district court's grant of summary judgment in favor of the plaintiffs, Committee of Dental Amalgam Alloy Manufacturers and Distributors and Dentsply International, Inc. (collectively the "manufacturers"). The district court held that, as applied to dental amalgam, the Medical Device Amendments to the federal Food, Drug and Cosmetics Act ("MDA"), 21 U.S.C. § 321-394, preempt California's Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65"), Cal. Health and Safety Code §§ 25249.5-25249.13. The district court had jurisdiction under 28 U.S.C. § 1331. This court has jurisdiction under 28 U.S.C. § 1291. We reverse.

BACKGROUND

Proposition 65 was passed by the voters of California in 1986. Proposition 65 mandates that the public be informed about products that pose a health risk. Proposition 65 specifically states:

> No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual.

Cal. Health & Safety Code § 25249.6.

Similarly, Congress enacted the MDA "to assure the reasonable safety and effectiveness of medical devices intended for human use." *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1455 (9th Cir. 1995) (citing H. Conf. Rep. No. 1090, 94th Cong., 2d Sess. *reprinted in* 1976 U.S. Code Cong. & Admin. News 1070, 1103). Manufacturers of medical devices are required to register each medical device with the federal Food and Drug Administration ("FDA") prior to commencing manufacture. 21 U.S.C. § 360(c). Failure to register a device is punishable by fines, penalties, and/or imprisonment. 21 U.S.C. § 333.

The MDA grants the FDA broad authority to regulate medical devices. 21 U.S.C. § 371(a). Under the MDA, the FDA must classify medical devices into three categories, according to the level of regulatory control the FDA determines is necessary to ensure the safety and effectiveness of each device. *See* 21 U.S.C. § 360c. Medical devices which pose little or no threat to public health are classified as Class 1 devices and are subject to only "general controls" related to their manufacture. *See* 21 U.S.C. § 360c(a)(1)(A); 21 C.F.R. § 860.3(c)(1). Medical devices which involve some risk of injury are classified as Class II devices and are subject to "special controls," including performance standards, use guidelines, and post-market surveillance programs. *See* 21 U.S.C. § 360c(a)(1)(B); 21 C.F.R. § 860.3(c)(2). Medical devices that pose a high risk of injury or that are implanted in the body are classified as Class III devices and must receive premarket approval from the FDA. *See* 21 U.S.C. §§ 360c(a)(1)(C), 360e; 21 C.F.R. §§ 814.1(c), 860.3(c)(3).

Dental amalgam is used by dentists to restore teeth. On July 1, 1990, pursuant to Proposition 65, the State of California listed mercury as a chemical known to cause reproductive harm. 22 Cal. Code of Regulations § 12000(c). As a result, consumer warnings for dental amalgam are now required. This requirement is satisfied through "general methods such as labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable." Cal. Health & Safety Code § 25249.11(f).

On September 21, 1993, the manufacturers filed this action seeking a judgment declaring Proposition 65 preempted by the MDA as it applied to dental amalgam. On November 5, 1993, the State filed a motion to dismiss or, in the alternative, for summary judgment. The manufacturers responded by also filing a motion for summary judgment. On August 25, 1994, the district court denied the State's motion and granted the manufacturers' motion for summary judgment on preemption grounds. The district court entered judgment in the manufacturers' favor on September 27, 1994.

Both the State and ELF timely filed separate notices of appeal. On October 11, 1994, the State initiated its appeal. ELF initiated its appeal on October 18, 1994. Both appeals were consolidated on January 6, 1995.

DISCUSSION

I. STANDARD OF REVIEW

We review de novo "the district court's grant of summary judgment on a pure question of law, in which there are no disputed facts." *Kennedy*, 67 F.3d at 1455 (citing *Turner v. Prod*, 707 F.2d 1109, 1114 (9th Cir. 1983)). Further, where, as here, the validity of a statute is being challenged, there must be a showing "that no set of circumstances exists under which the . . . [statute] would be valid." *Chemical Specialties*

Mfrs. Ass'n, Inc. v. Allenby ("*Allenby*"), 958 F.2d 941, 943 (9th Cir. 1992) (" 'the fact that the . . . Act might operate unconstitutionally under some conceivable set of circumstances is insufficient to render it wholly invalid' ") (quoting *United States v. Salerno*, 481 U.S. 739, 745 (1987)). Thus, to find that Proposition 65 is preempted by the MDA, we "must determine that all possible consumer product warnings that would satisfy Proposition 65 conflict with provisions of the" MDA. *Id.* (emphasis added).

II. WHETHER DENTAL MERCURY IS A "MEDICAL DEVICE" UNDER THE MDA

The district court assumed that dental amalgam is regulated by the MDA as a "medical device" because its two component parts—dental mercury and amalgam alloy—are classified by the MDA. As the district court explained:

> The court need not consider whether the FDA is treating dental amalgam as a device, whether it believes it is regulating dental amalgam, or whether it intends to regulate dental amalgam. The court finds, as a matter of logic, that any regulation of dental mercury will, ipso facto, regulate any product containing dental mercury, including dental amalgam. Therefore, this court's ruling extends to dental amalgam. The court need not reach amalgam alloy as Proposition 65 does not regulate it.

Thus, as a threshold matter, we must decide whether the district court was correct in holding that the MDA applied to dental amalgam. Congress defined the term "medical device" very broadly as:

> [a]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article including any component, parts or accessory, which is—

> (1) recognized in the official National Formulary, or the United States Phamacopeia, or any supplement to them,
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C. § 321(h) (emphasis added).

Based on this broad definition of "medical device," we hold that dental amalgam does fall within the reach of the MDA. Dental amalgam is used in the treatment and prevention of tooth decay. Further, the FDA has already classified the component parts of dental amalgam. Dental mercury is classified as a Class 1 device. 21 C.F.R. § 872.3700. Amalgam alloy is classified as a Class II device. 21 C.F.R. § 872.3050. Thus, there can be no question that any regulation of dental mercury or amalgam alloy under the MDA also applies to dental amalgam.

III. GENERAL PREEMPTION PRINCIPLES

There is a strong presumption against finding that state law is preempted by federal law. *Allenby*, 958 F.2d at 943. As the Supreme Court recently stated:

> [B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action. In all pre-emption cases, and particularly in those in which Congress has "legislated . . . in a field which the States have traditionally occupied," . . . we "start with the as-

> sumption that the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress."

Medtronic, Inc. v. Lohr, ___ U.S. ____, 116 S. Ct. 2240, 2249 (1996) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Thus, "States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Id.* at 2245 (citations and quotations omitted).

In addition, a court's analysis as to the scope of preemption is guided by Congress's purpose in enacting the statute at issue. *Id.* at 2250. Congress's purpose "is discerned from the language of the pre-emption statute and the 'statutory framework' surrounding it" as well as from "the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers and the law." *Id.* (citations omitted).

IV. PREEMPTION UNDER THE MDA

Congress included an explicit preemption provision in the MDA. Section 360k(a) provides:

> [N]o state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) *which is different from, or in addition to,* any requirement applicable under this chapter to the device, and
>
> (2) *which relates to the safety or effectiveness of the device* or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis added).

In *Medtronic v. Lohr*, the Supreme Court rejected a broad construction of this preemption provision. In *Medtronic*, the

manufacturer of a Class III device was sued under state law for damages caused by a defective pacemaker. The manufacturer argued that plaintiff's state causes of action were preempted by the MDA because they qualified as state "requirement[s] . . . different from . . . [and] in addition to" the federal standards and "requirements" promulgated by the FDA. *Id.* at 2250.

The Supreme Court found the manufacturer's arguments "not only unpersuasive . . . [but also] implausible." *Id.* As the Supreme Court explained:

> Under Medtronic's view of the statute, Congress effectively precluded state courts from affording state consumers any protection from injuries resulting from a defective medical device. Moreover, because there is no explicit private cause of action against manufacturers contained in the MDA, and no suggestion that the Act created an implied private right of action, Congress would have barred most, if not all, relief for persons injured by defective medical devices. . . . Medtronic's construction of § 360k would therefore have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation . . . . It is, to say the least, "difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct," . . . and it would take language much plainer than the text of § 360k to convince us that Congress intended that result.

Id.

Based on this reasoning, we hold that our prior decisions narrowly construing the MDA's preemption clause are consistent with *Medtronic v. Lohr*. Before Medtronic, we already had rejected a broad construction of the MDA preemption clause. *See Kennedy v. Collagen*, 67 F.3d 1453, 1457 (9th

Cir. 1995); *Anguiano v. E.I. DuPont de Nemours & Co.*, 44 F.3d 806, 809 (9th Cir. 1995). As we explained in *Kennedy*:

> [T]he statutory language of § 360k(a) does not create the broad, sweeping preemption found by . . . [other circuits]. Reading 360k(a)(1) broadly requires recognizing that *any* state law is, by definition, a law "in addition to" federal law. A broad reading of § 360k(a) thus renders the "different from" language meaningless and forces a strained reading of the statute.

Id.

Further, in determining what kind of federal "requirement" and what kind of state "requirement" trigger preemption, the Supreme Court in *Medtronic* deferred to the FDA's regulation that narrowly construes the MDA's preemption clause. 116 S. Ct. at 2260-63. Section 808.1(d) provides, in relevant part:

> State or local requirements are preempted *only* when the Food and Drug Administration has established *specific counterpart* regulations or there are other *specific* requirements applicable to a *particular* device under the act, thereby making any existing divergent State or local requirements applicable to the device different from or in addition, the *specific* Food and Drug Administration requirement . . . .

21 C.F.R. § 808.1(d) (emphasis added).

Based on this FDA regulation, a state or local "requirement" is preempted by the MDA only if specific counterpart requirements or regulations that are applicable to a *particular* device exist. As the Supreme Court explained:

> [P]reemption under the MDA does not arise directly as a result of the enactment of a [state] statute; rather, in most cases a state law will be preempted only to the extent that

> the FDA has promulgated a relevant federal "requirement."

116 S. Ct. at 2255. *See also Anguiano v. E.I. DuPont de Nemours & Co.*, 44 F.3d 806, 809 (9th Cir. 1995) ("the scope of preemption is limited to instances where there are *specific* FDA requirements applicable to a *particular* device") (emphasis added).[1]

In addition, the Supreme Court in *Medtronic* specifically approved that part of the FDA regulation that provides that "[s]ection 521(a) does not preempt State and local requirements of *general applicability* where the purpose of the requirement relates either to other products in addition to devices . . . or to unfair trade practices in which the requirements are not limited to devices." 21 C.F.R. § 808.1(d). As the Supreme Court explained, the word "[r]equirement appears to presume that the State is imposing a *specific* duty upon the manufacturer." 116 S. C. at 2251 (emphasis added). Thus, a state law of general applicability will be preempted only if it has "the effect of establishing a substantive requirement for a specific device." *Id.* at 2262.

V. WHETHER PROPOSITION 65 IS PREEMPTED BY THE MDA

The district court held that, even though the FDA has not established "specific" regulations relating to dental amalgam, the MDA still preempts Proposition 65. First, the district court held that 21 C.F.R. § 801.109, the FDA regulation describing the manufacturing and labeling requirements, is

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[1] In 1990 and 1992, Congress amended the MDA while leaving 21 C.F.R. § 808.1(d) intact. If Congress disagreed with the FDA's interpretation of the MDA's preemption clause, Congress would have amended the MDA at that time. Because Congress did not do so, it is fair to assume that the FDA's interpretation of the MDA's preemption clause is consistent with Congressional intent.

"specific" enough to trigger preemption. Second, the district court held that the FDA's alleged refusal to impose reproductive toxicity requirements on dental mercury is by itself preemptive.

The district court was wrong on both counts. In *Medtronic*, the Supreme Court held that the FDA's manufacturing and labeling requirements were *not* "specific" enough to preempt state law. 116 S. Ct. at 2263. As the Supreme Court explained:

> The generality of those requirements make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers. Rather, the federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements.

116 S. Ct. at 2257.

Further, Proposition 65 is a state law of general applicability which was *not* enacted "with respect to" medical devices. Proposition 65 applies to *all* products and services that pose a health risk to the public. Except for identifying chemicals known to pose a health risk, Proposition 65 is not directed at any product or industry. Nor has the State of California adopted any *specific* regulation or requirement that relates to dental amalgam. The State of California has listed mercury as a product which causes reproductive harm. As a result, consumer warnings for dental amalgam are now required.

Thus, we hold that the consumer warning requirement under California's Proposition 65 is not "specific" enough to trigger preemption because it is "not the kind[] of requirement[] that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements." 116 S. Ct. at 2257. As the Supreme Court explained in *Medtronic*:

> General obligations are not more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in training and supervision of a workforce. These state requirements therefore escape preemption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be "with respect to" specific devices.

Id.

We also reject the district court's holding that the FDA's *failure* to impose a warning requirement on dental amalgam is by itself preemptive. Inherent in the term "requirement" is the idea that there be a positive enactment from the FDA before preemption can be triggered. As the Supreme Court explained in *Medtronic*:

> [T]he word ["requirement"] is linked with language suggesting that its focus is device-specific enactments of positive law by legislative or administrative bodies. . . . For instance, subsections (a)(2) and (b) of the statute also refer to "requirements"—but those "requirements" refer only to statutory and regulatory law that exists pursuant to the MDA itself, suggesting that the pre-empted "requirements" established or continued by States also refer primarily to positive enactments of state law.

116 S. Ct. at 2252.

To hold that inaction by the FDA is sufficient to trigger preemption would mean that manufacturers would be free to ignore state laws that are intended to protect consumers, during the period that the FDA is considering whether to issue specific regulations relating to particular products, or after the FDA, for whatever reason, has "decided," through inaction, not to regulate particular products. Such a holding would contradict Congress's stated intent of providing consumer protection from unsafe medical devices when it enacted the MDA. *See* 43 Fed. Reg. 18,663 (May 2, 1978).

CONCLUSION

As set forth above, the district court's grant of summary judgment in favor of plaintiffs is reversed. We conclude that California's Proposition 65 is not preempted by the MDA.

REVERSED AND REMANDED.

[unreported]

FILED
SEP 16 1994
CLERK, U.S. DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA
BY /s/ DEPUTY

United States District Court
Southern District of California

COMMITTEE OF DENTAL AMALGAM ALLOY MANUFACTURERS, et al., Plaintiffs,

vs.

DR. CAROL HENRY, et al., Defendants.

ENVIRONMENTAL LAW FOUNDATION, Intervenor.

Civil No. 93-1439-B(BTM)

ORDER AMENDING PREVIOUS ORDER OF 8/24/94 TO DENY PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT ON ISSUE OF COMMERCE CLAUSE AS MOOT

The court hereby orders that this court's order filed on August 24, 1994, and bearing the caption "ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT ON ISSUE OF PREEMPTION; DENYING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT ON ISSUE OF COMMERCE CLAUSE VIOLATION; DENYING DEFENDANTS' AND INTERVENOR'S MOTIONS TO DISMISS OR FOR SUMMARY JUDGMENT; AND DENYING DEFENDANTS' MOTIONS TO STRIKE AND FOR DISCOVERY," be amended by this order.

Sections IV and V(2) of the August 24, 1994 order are amended to reflect that the plaintiffs' motion for summary judgment on its declaratory relief claim based on a violation of the Commerce Clause is denied as moot.

IT IS SO ORDERED.

DATED: SEP 15 1994

/s/

UNITED STATES DISTRICT JUDGE

cc: All Parties

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[reported at 871 F. Supp. 1278]

FILED
AUG 24 1994
CLERK, U.S. DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA
BY DEPUTY

United States District Court
Southern District of California

COMMITTEE OF DENTAL AMALGAM ALLOY MANUFACTURERS, et al., Plaintiffs,

vs.

DR. CAROL HENRY, et al., Defendants.

ENVIRONMENTAL LAW FOUNDATION, Intervenor.

Civil No. 93-1439-B(BTM)

ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT ON ISSUE OF PREEMPTION;

DENYING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT ON ISSUE OF COMMERCE CLAUSE VIOLATION;

DENYING DEFENDANTS' AND INTERVENOR'S MOTIONS TO DISMISS OR FOR SUMMARY JUDGMENT; AND

DENYING DEFENDANTS' MOTIONS TO STRIKE AND FOR DISCOVERY

Plaintiffs' motion for summary judgment, defendants' and intervenor's motions to dismiss, or in the alternative for summary judgment, and defendants' motions to strike the declaration of David Link and for additional discovery, were heard before the Honorable Rudi M. Brewster on May 16, 1994. Stanley Landfair, Esq., and Carol Brophy, Esq., appeared for plaintiffs; Susan Fiering, Esq., appeared for the

State defendants; James Wheaton, Esq., and Alice Chang Kaufman, Esq., appeared for the intervenor defendant. The court continued these motions for supplemental briefing and further review. Upon further consideration of the moving and responding papers, the supplemental briefs and submissions,[1] the court hereby GRANTS summary judgment for plaintiffs on the issue of preemption, DENIES plaintiff's motion for summary judgment on the Commerce Clause claim, and DENIES defendants' motions.

I. Background

Plaintiffs brought this declaratory and injunctive relief action seeking a determination that a California state statute, the California Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65"), Cal. Health & Safety Code §§ 25249.5-25249.13, is preempted by the Medical Device Amendments ("MDA") of 1976 to the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. §§ 321-394, in so far as Proposition 65 imposes warning requirements for dental mercury that are different from or in addition to requirements under the MDA. Plaintiffs also contend that Proposition 65 violates the Commerce Clause.

Proposition 65 states:

> **§ 25249.6. Required warning before exposure to chemicals known to cause cancer or reproductive toxicity**
>
> No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical

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[1] The court requested supplemental briefs, of no more than ten pages, on the issue of labelling. The court declines to consider plaintiffs' June 7, 1994, letter because it exceeds the court's request. The court accepts ELF's May 12, 1994, letter and plaintiff's May 23, 1994, letter, because they cite recently-decided authority. The court accepts all three supplemental briefs.

> known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10.
>
> **§ 25249.10. Exemptions from warning requirement**
>
> Section 25249.6 shall not apply to any of the following: (a) An exposure for which federal law governs warning in a manner that preempts state authority . . . [or] (c) An exposure for which the person responsible can show that the exposure poses no significant risk . . . .

The State of California has listed dental mercury as a "chemical known to the state to cause . . . reproductive toxicity."

All medical devices are classified under the MDA. Dental mercury is a Class I device regulated by the MDA. *See* 21 C.F.R. § 872.3700(b). The federal Food and Drug Administration ("FDA") has defined dental mercury as "a device composed of mercury intended for use as a component of amalgam alloy in the restoration of a dental cavity or a broken tooth." *Id.* Amalgam alloy is a Class II device. *See* 21 C.F.R. § 872.3050. Dental amalgam, which is the combination of dental mercury and amalgam alloy, is not a "device" under the MDA. However, to the extent that its two component parts are regulated by the MDA, dental amalgam is, ipso facto, regulated by the MDA.[2]

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[2] The court need not consider whether the FDA is treating dental amalgam as a device, whether it believes it is regulating dental amalgam, or whether it intends to regulate dental amalgam. The court finds, as a matter of logic, that any regulation of dental mercury will, ipso facto, regulate any product containing dental mercury, including dental amalgam. Therefore, this court's ruling extends to dental amalgam. The court need not reach amalgam alloy as Proposition 65 does not regulate it.

All medical devices, whether Class I, II, or III, are subject to "general controls." *See* 21 U.S.C. § 360c(a)(1)(A). The general controls include a provision for labeling and warnings. *See* 21 U.S.C. § 352(f). Section 352(f) states:

> A drug or device shall be deemed to be misbranded—
>
> . . . Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

The Secretary has promulgated regulations exempting prescription devices from the requirement of clause (1). *See* 21 C.F.R. § 801.109.[3] Section 801.109 states, in relevant part:

> A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section

---

[3] From oral argument, the court understands that dental mercury and amalgam alloy traditionally were mixed in the dentist's office, but more recently are sold pre-packaged in capsule form. The court requested plaintiffs to submit a sample of labelling for dental amalgam capsules to enable it to understand the application of this regulation to dental mercury, not to determine whether plaintiffs' labelling complies with the regulation, which is not at issue in this case.

502(f)(1) [352(f)(1)] of the act if all of the following conditions are met:

(a) The device is:

(1) (i) In the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or

(ii) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device; and

(2) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

(b) . . .

(c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented: *Provided, however*, That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

(d) . . .

(e) . . . .

In addition, the statute provides that the FDA has the authority to impose any necessary warning requirements on medical devices. *See* 21 U.S.C. § 360h(a). The relevant part of § 360h(a) states:

> If the Secretary determines that—
>
> (1) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health, and
>
> (2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk,
>
> the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all health professionals who prescribe or use the device and to any other person (including manufacturers, importers, distributors, retailers, and device users) who should properly receive such notification in order to eliminate such risk. . . .

There is no genuine issue of material fact that the FDA has considered, and rejected, imposing reproductive toxicity warning requirements for dental amalgam. *See* Brophy Decl., Exhs. 5, 7, 14, 17, 28-31, 33; Link Decl. at 60- 61;[4] 40 Fed.

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[4] Defendants have moved to strike the Declaration of David Link, who managed the FDA's medical device program from 1970 to 1980. This motion is DENIED. Defendants also have requested that the court grant them leave to conduct additional discovery on the FDA's consideration of, and rejection of, warnings for reproductive toxicity. This request also is DENIED. Defendants had ample opportunity to conduct discovery, as this motion was continued several times at the parties' request. Furthermore, FDA's consideration of imposing reproductive toxicity (Footnote continued on next page)

Reg. 21,848 (May 19, 1975); 42 Fed. Reg. 60,193 (Nov. 29, 1977).

II. Preemption Standards

The MDA contains an explicit preemption provision. *See* 21 U.S.C. § 360k. Section 360k states:

> **(a) General rule**
>
> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.[5]
>
> **(b) Exempt requirements**
>
> Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—
>
> (1) the requirement is more stringent than a requirement under this chapter which would be applica-

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(Footnote continued from previous page)
warning requirements is not an issue which should have taken defendants by surprise.

[5] There is no question that Proposition 65 "relates" to the safety of dental mercury.

> ble to the device if an exemption were not in effect under this subsection; or
>
> (2) the requirement—
>
> (A) is required by compelling local conditions, and
>
> (B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

The State of California has not received an exemption from § 360k(a).

The Supreme Court has established the standard a district court applies when faced with a statutory preemption provision. *See Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992). It said:

> When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a "reliable indicium of congressional intent with respect to state authority," . . . "there is no need to infer congressional intent to pre-empt state laws from the substantive provisions" of the legislation.

Id. at 2618. Therefore, the court looks only to the explicit preemption provision at § 360k(a), not to legislative history of congressional intent. The court also said:

> Congress' enactment of a provision defining the preemptive reach of a statute implies that matters beyond that reach are not preempted. . . . Therefore, we need only identify the domain expressly pre-empted by [the pre-emption provisions].

Id. Pursuant to *Cipollone*, then, this court's task is to determine the preemptive reach of § 360k(a); that is, whether § 360k(a) extends to state reproductive toxicity warning re-

quirements for dental mercury or products containing dental mercury.

There is a general presumption against preemption, particularly in the regulation of health and safety matters, which are "primarily, and historically, a matter of local concern." *Chemical Specialties Manufacturers Ass'n, Inc. v. Allenby*, 958 F.2d 941, 943 (9th Cir. 1992), *cert. denied*, 113 S. Ct. 80 (1992). This presumption applies even when a statute contains an explicit preemption provision. *See Cipollone*, 112 S. Ct. at 2618 ("we must construe these provisions in light of the presumption against preemption"). Therefore, if the court were to find that the preemptive reach of § 360k(a) is not clear from a reading of the statute, the presumption against preemption would encourage this court to construe the preemption provision narrowly.

Here, the preemptive reach of § 360k(a) is clarified by FDA regulation.[6] *See* 21 C.F.R. § 808.1(d). Section 808.1(d) states:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) [360k(a)] of the act because they are not

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[6] The FDA's interpretation of § 360k(a) is controlling, so long as it is not contrary to congressional intent. *King v. Collagen Corp.*, 983 F.2d 1130, 1134-35 (1st Cir. 1993). Neither party has contested the validity of the regulations.

> "requirements applicable to a device" within the meaning of section 521(a) [360k(a)] of the act.

The regulation cites various examples of State or local requirements that are not regarded as preempted. The example relevant to this case is as follows:

> (1) Section 521(a) [360k(a)] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

See 21 C.F.R. § 808.1(d)(1).

III. Preemption

As discussed above, the MDA and its regulations do not impose a specific reproductive toxicity warning requirement on dental mercury. Therefore, it is clear that the FDA has not established "specific counterpart regulations" which would preempt state reproductive toxicity warning requirements. *See* 21 C.F.R. § 808.1(d). However, the language of the regulation makes clear that the MDA need not include a counterpart regulation in order to preempt state law. The issues remaining, then, are (1) whether "there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements," or (2) whether Proposition 65 is a "requirement of general applicability." *Id.*

A. Other Specific Requirements

The court finds there are "other specific requirements applicable to" dental mercury under the MDA and its regulations which render Proposition 65's warning requirement

"different from, or in addition to" the MDA's requirements. First, the FDA's refusal to impose a reproductive toxicity warning requirement on dental mercury is preemptive. Defendants[7] have argued that only an express provision of the MDA or its regulations can be preemptive. The court finds that the FDA's decision not to impose such a warning requirement must not be viewed as silence or as a failure to regulate. The MDA contains a specific provision granting the FDA the authority to impose such requirements, and the FDA affirmatively chose not to impose a reproductive toxicity warning requirement. *See* 21 U.S.C. § 360h. Given the FDA's authority to impose such a requirement, its decision was an exercise of that authority. Proposition 65 imposes a warning requirement which is different from the FDA's decision.

Second, the MDA also contains a specific requirement that medical devices, including dental mercury, bear adequate directions for use and adequate warnings. *See* 21 U.S.C. § 352(f). For prescription devices, the FDA has imposed specific requirements for an exemption from § 352(f), which includes a requirement that labelling bear information regarding "any relevant hazards, contra-indications, side effects, and precautions." Information regarding reproductive hazards would fall within this type of information. The parties do not dispute that dental mercury is a prescription device. The regulations state that prescription devices are "not safe except under supervision of a practitioner," such as a dentist. *See* 21 C.F.R. § 801.109. The regulation states that "adequate directions for use" *cannot* be prepared for such a device. As a result, devices such as dental mercury, must either comply with the specific warning provisions of 21

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[7] In this section, the court will use "defendants" to mean defendants and intervenor defendants.

C.F.R. § 801.109 or violate § 352(f). Proposition 65 imposes a warning requirement in addition to these requirements.

Defendants contend that these provisions are not "specific requirements" applicable to dental mercury, as they fall within the general controls applicable to all medical devices. Defendants point to several examples of warning requirements which apply only to one specific device. *See, e.g.*, 21 C.F.R. § 801.403; *see also* ELF's Motion, Exh. A. Defendants argue that § 808.1(d) contemplates this degree of specificity before it will preempt. Defendants read § 808.1(d) too narrowly. Section 808.1(d) does not state that the MDA preempts state law only when it contains a requirement specifically applicable to one specific device. A "specific requirement" may apply to numerous medical devices and still be preemptive. *See Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421 (5th Cir.) (premarket approval procedure, applicable to all Class III devices, preempts state tort claims for defective design, inadequate warning and negligent failure to warn), *cert. denied*, 114 S. Ct. 86 (1993); *see also King v. Collagen Corp.*, 983 F.2d 1130, 1134-35 (1st Cir. 1993) (approval of device's labelling and packaging during Class III premarket approval process preempts state tort claims), *cert. denied*, 114 S. Ct. 84 (1993).

At the heart of this dispute is the fact that dental mercury, as a Class I device, is subject only to the requirements stated in the general controls and their attendant regulations. Neither party has cited a preemption case involving a Class I device, and the court has found none. Therefore, it appears that there is no authority directly on point. Defendants argue that if the general controls regulating a Class I device can be preemptive, "[t]he mere act of designating an item as a medical device would automatically deprive the states of all regulatory power over" that item. As a result, the argument goes, there would be no need for the word "specific" in § 360k(a) and § 808.1(d).

It is not dispositive that dental mercury is only a Class I device or that this court will be the first to find preemption in a case involving a Class I device. Since all medical devices are subject to the general controls, the court is just as persuaded by cases analyzing the preemptive effect of general controls on Class II or Class III devices. It appears to the court that the parties have cited only two published cases addressing the preemptive effect of general controls, and both cases found preemption. *See Mendes v. Medtronic*, 18 F.3d 13 (1st Cir. Mar. 9, 1994) (§ 801.109 preempts state tort claim based on manufacturer's failure to warn of pacemaker's latent defects); *Hunsaker v. Surgidev Corp.*, 818 F. Supp. 744 (M.D. Penn. 1992) (§ 360h preempts state tort claim based on manufacturer's failure to notify of defects), *aff'd*, 5 F.3d 1489 (3d Cir. 1993).

Therefore, for the reasons stated here and in *Mendes* and *Hunsaker*, the court hereby finds that Proposition 65's warning requirements, when imposed on dental mercury or products containing dental mercury, are different from, or in addition to, specific MDA requirements applicable to dental mercury or products containing dental mercury, and consequently are preempted.

B. Requirement of General Applicability

Alternatively, defendants argue that Proposition 65 is merely a state requirement of "general applicability" that "affects" devices but is not a "requirement applicable to a device" within the meaning of the MDA. *See* 21 C.F.R. § 808.1(d)(1). The court rejects the notion that Proposition 65 is akin to electrical codes or the Uniform Commercial Code. A state warning requirement relating to the safe use of chemicals is more akin to a state tort law relating to the safety of products and their use, *see Needham v. Int'l Playtex, Inc.*, 1989 U.S. Dist. LEXIS 800 (E.D. Ky. 1989), than it is to general codes which relate to the safety of public space or to the legal rights of consumers.

IV. Commerce Clause

Plaintiffs claim that Proposition 65 violates the Commerce Clause. To determine whether a state statute violates the Commerce Clause, a court must examine "whether the State's interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits." *Brown-Forman Distillers v. New York*, 476 U.S. 573, 579 (1986). A court may properly strike down a state statute if its purpose is to disfavor interstate commerce, if its benefits are illusory or insignificant, or if the particular means chosen to achieve its goals are "irrational, arbitrary or unrelated to those goals." *Alaska Airlines, Inc. v. City of Long Beach*, 951 F.2d 977, 984 (9th Cir. 1991).

Plaintiffs' motion for summary judgment on this claim fails for two reasons. First, plaintiffs' have not submitted sufficient evidence for this court to rule, as a matter of law, that Proposition 65 places an unconstitutional burden on interstate commerce. Second, this issue is riddled with genuine issues of material fact. For instance, ELF argues that plaintiffs' claim that compliance with Proposition 65 is unduly burdensome lacks credibility in light of a recent voluntary settlement agreement in *Environmental Law Foundation v. Jeneric/Pentron*, San Francisco Superior Court No. 957039 (Dec. 13, 1993). However, John C. Miles, president of plaintiff Dentsply Int'l, Inc., and Gordon Cohen, president of Jeneric/Pentron, have submitted declarations stating that compliance with Proposition 65 is so burdensome that they may have to relocate their businesses to another state. *See* Miles Decl.; Moran Decl., Exh. 4. Cohen states that Jeneric/Pentron was forced to settle with ELF.

Based on *Brown-Forman*, *Alaska Airlines*, and the evidence submitted, the court cannot now say, as a matter of law, that Proposition 65 does or does not violate the Commerce Clause. Therefore, plaintiffs' motion for sum-

mary judgment on their Commerce Clause claim is DENIED, without prejudice.

V. Conclusion

For the foregoing reasons, the court hereby orders that:

1. Plaintiffs' motion for summary judgment on its declaratory and injunctive relief claims based on preemption is GRANTED;

2. Plaintiffs' motion for summary judgment on its declaratory relief claim based on a violation of the Commerce Clause is DENIED;

3. Defendants' motion to dismiss, or in the alternative, for summary judgment, is DENIED;

4. Intervenor defendant's motion to dismiss, or in the alternative, for summary judgment, is DENIED;

5. Defendants' motions to strike and for additional discovery are DENIED.

IT IS SO ORDERED.

DATED: AUG 23 1994

/s/

UNITED STATES DISTRICT JUDGE

cc: Susan S. Fiering, Esq.
Deputy Attorney General
State of California
Department of Justice
2101 Webster Street, 12th Floor
Oakland, California 94612-3049

James Wheaton, Esq.
Alice Chang Kaufman, Esq.
Environmental Law Foundation
California Building
1736 Franklin Street, 8th Floor
Oakland, California 94612

Stanley W. Landfair, Esq.
Carol Brophy, Esq.
McKenna & Cuneo
444 S. Flower Street, 8th Floor
Los Angeles, California 90017-2909

Richard G. Opper, Esq.
McKenna & Cuneo
750 B Street, Suite 3200
San Diego, California 92101

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21 U.S.C. § 360k (1994)

§ 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 C.F.R. § 808.1(d) (1995) (excerpt)

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

. . . .

(2)

No. 96-705

FILED
DEC 5 1996
CLERK

IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1996

COMMITTEE OF DENTAL AMALGAM ALLOY MANUFACTURERS AND DISTRIBUTORS AND DENTSPLY INTERNATIONAL, INC., *Petitioners*,

v.

RICHARD A. BECKER, DIRECTOR OF THE OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT, DANIEL E. LUNGREN, ATTORNEY GENERAL OF THE STATE OF CALIFORNIA, AND ENVIRONMENTAL LAW FOUNDATION, *Respondents*.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

RESPONDENTS' BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

DANIEL E. LUNGREN
Attorney General
RODERICK E. WALSTON
Chief Assistant Attorney General
THEODORA BERGER
Assistant Attorney General
CRAIG C. THOMPSON
EDWARD G. WEIL
SUSAN S. FIERING*
Deputy Attorneys General
(*Counsel of Record)
2101 Webster St., 12th Floor
Oakland, CA 94612-3049
Telephone: (510) 286-3892
Attorneys for Respondents

50 pp

QUESTION PRESENTED

On June 26, 1996, this Court decided in *Medtronic* v. *Lohr*, __ U.S. __, 116 S. Ct. 2240 (1996), that the prescription device labeling requirements of the Medical Device Amendments to the Federal Food, Drug and Cosmetics Act, contained in 21 C.F.R. section 801.109, were too general to preempt common law failure to warn claims; and that common law failure to warn claims were not developed "with respect to" medical devices and therefore were not the type of state requirements that Congress and the FDA intended to be preempted by the MDA. The question presented here is:

Whether, in light of this Court's decision in *Medtronic* v. *Lohr*, the prescription device labeling requirements contained in 21 C.F.R. section 801.109 of the Medical Device Amendments are too general to preempt a California warning statute that is a statute of general applicability directed at chemicals and not developed with respect to medical devices?

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IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1996
No. 96-705

COMMITTEE OF DENTAL AMALGAM ALLOY MANUFACTURERS AND DISTRIBUTORS AND DENTSPLY INTERNATIONAL, INC., *Petitioners*,

v.

RICHARD A. BECKER, DIRECTOR OF THE OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT, DANIEL E. LUNGREN, ATTORNEY GENERAL OF THE STATE OF CALIFORNIA, AND ENVIRONMENTAL LAW FOUNDATION, *Respondents*.

Dr. Richard Becker, the Director of the California Office of Environmental Health Hazard Assessment ("OEHHA") and California Attorney General Daniel E. Lungren (hereinafter "State Parties") submit this opposition to the Petition for Writ of Certiorari filed by the Committee of Dental Amalgam Alloy Manufacturers and Distributors and Dentsply International Inc. (hereinafter "Dental Parties"). The Petition seeks review of a decision of the Ninth Circuit Court of Appeals holding that Proposition 65, a state "Right-to-Know" warning statute, is not preempted by the provisions of the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetics Act.

The Ninth Circuit decision is the only circuit court opinion to date discussing preemption under the MDA that has had the benefit of this Court's recent rulings in *Medtronic* v. *Lohr*, __ U.S. __, 116 S.Ct. 2240 (1996). The Ninth Circuit opinion addresses the same statute and regulations that were at issue in *Medtronic* and is absolutely consistent with this Court's opinion in that case.

OPINIONS BELOW

The opinion of the Court of Appeals for the Ninth Circuit is reported at 92 F.3d 807 (9th Cir. 1996). The opinion of the United States District Court for the Southern District of California is reported at 871 F.Supp. 1278 (S.D. Cal. 1994).

JURISDICTION

The Court of Appeals entered judgment on August 5, 1996. This Court has jurisdiction under 28 U.S.C. section 1254(1).

STATUTORY AND REGULATORY PROVISIONS

The following statutory and regulatory provisions are set forth in the Appendix to the Opposition to Petition for Writ of Certiorari ("Oppos. App."): 21 U.S.C. §§ 360(k), 360h(a), 371(a), 21 C.F.R. §§ 808.1(d), 801.109, 895.25; and California Health & Safety Code § 25249.6.

STATEMENT OF THE CASE

The Ninth Circuit's decision was issued a month after and followed directly from this Court's decision in *Medtronic* v. *Lohr*, __ U.S. __, 116 S.Ct. 2240 (1996).[1] Relying on *Medtronic*, the Ninth Circuit held that the prescription device labeling requirements contained in 21 C.F.R. section 801.109 (the same requirements at issue in *Medtronic*) were not sufficiently specific to preempt state warning requirements contained in California's Safe Drinking Water and Toxic Enforcement Act of 1986, California Health & Safety Code section 25249.5 *et seq.* ("Proposition 65"). The Ninth Circuit also ruled that Proposition 65 was a state law of general applicability not directed at medical devices and therefore not preempted; and that preemption under the MDA occurs only when the Food and Drug Administration ("FDA") has imposed a requirement, and not when the FDA has simply failed to impose a warning.

Not only was the Ninth Circuit's opinion based directly on *Medtronic*, it is the first circuit court opinion to have applied the *Medtronic* analysis to the question of preemption under the MDA.

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1. The State of California submitted a Brief Amicus Curiae to this Court in the *Medtronic* case, explaining Proposition 65 and the issues presented in this case.

A. The Relevant Statutes

1. Medical Device Amendments to the Food, Drug and Cosmetics Act

The Federal Food, Drug and Cosmetics Act ("FDCA") was enacted in order to keep interstate commerce free from deleterious, adulterated and misbranded articles of specified types. *U.S.* v. *Walsh,* 331 U.S. 432, 434 (1947). In 1976 Congress passed the Medical Device Amendments ("MDA") to the FDCA and gave the FDA the "authority to promulgate regulations for the efficient enforcement of the chapter. . ." 21 U.S.C. § 371(a).

As part of the MDA, Congress enacted an express preemption provision in 21 U.S.C. section 360k(a) which provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement --
>
> 1) which is different from, or in addition to any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

The implementing regulations promulgated by the FDA make clear that the MDA preempts state regulation of a medical device only when there exist specific counterpart regulations or requirements applicable to the device.

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 808.1(d).

The regulations further recognize that certain state laws and regulations may affect devices but still not be preempted by the MDA:

> There are other State or local requirements that affect devices that are not preempted by section 521(a) [360(k)] of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) [360(k)] of the act.

Id. Non-preempted requirements are those of "general applicability":

> where the purpose of the requirement relates . . . to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)). . . .

21 C.F.R. § 808.1(d)(1).

Pursuant to its authority, the FDA promulgated certain general requirements that apply to all medical devices. The only requirement at issue here is the general control imposed under 21 C.F.R. section 801.109 which applies to all prescription devices and exempts them from the labeling requirements contained in 21 U.S.C. section 352(f). Section 801.109(c) states that manufacturers of prescription devices are exempt from the requirements of section 352(f) if, among other things, the device's labeling:

> bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended. . . .

At issue in this case is a medical device known as dental mercury,[2] defined in the MDA as "a device composed of mercury intended for use as a component of amalgam alloy in the restoration of a dental cavity or broken tooth." 21 C.F.R. § 872.3700. Dental mercury contains mercury, and exposes dentists and dental patients to mercury vapors.

While the FDA has absolute authority to promulgate additional specific warning requirements for medical devices or to prohibit warnings it believes to be improper, 21 U.S.C. § 371(a), 21 U.S.C. § 360h(a), 21 C.F.R. § 895.25, it has done neither with dental mercury.

2. Proposition 65

Proposition 65 is a state "Right to Know" statute, passed by the voters of California in 1986. It requires that the public be informed about exposures to certain listed chemicals that are carcinogens and/or reproductive toxins. Proposition 65 specifically states:

> No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual.

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2. The Ninth Circuit determined that dental amalgam is also regulated as a medical device in the MDA. *Committee of Dental Amalgam Alloy Manufacturers* v. *Stratton*, 92 F.3d 807, 810-11 (9th Cir. 1996).

Cal. Health & Safety Code § 25249.6.

Section 25249.10 provides that no warning is required when the person responsible can show that the exposure poses no significant risk or will have no observable effect.

Proposition 65 does not define the term warning, but explains that warnings may be provided "by general methods such as labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable." Health & Safety Code § 25249.11(f). The "safe harbor"[3] warning language for consumer products that contain reproductive toxins is: "**WARNING**: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm." 22 Cal. Code Reg. ("C.C.R.") § 12601(b).

Pursuant to California Health & Safety Code section 25249.7(c), the California Attorney General may sue in the name of the people of the State of California to enforce Proposition 65. In addition, private parties are authorized to enforce the provisions of the statute if they have given notice of the alleged violations to the Attorney General and the Attorney General does not file suit within sixty days after receipt of such notice. Cal. Health & Safety Code § 25249.7(d). The citizen suit

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3. Warnings that include the "safe harbor" language and employ methods of transmission set forth in the statute are deemed to be clear and reasonable. 22 Cal. Code Reg. § 12601(b).

provisions of Proposition 65 are modeled generally after a variety of federal environmental laws such as the Clean Water Act. *See* 33 U.S.C. § 1365(a)(1).

Mercury is a listed reproductive toxin under Proposition 65. 22 C.C.R. § 12601(c). The statute therefore requires that a manufacturer and/or distributor of a product that exposes individuals to mercury must provide the required warning. No warning is required if the manufacturers/distributors can show that the exposure poses no significant risk or will have no observable effect.

B. Background To This Litigation

The controversy arose in August, 1993, when the Environmental Law Foundation ("ELF"), a public interest environmental group, served citizen suit notices under Proposition 65 on Dentsply, Inc. and other manufacturers of dental mercury, notifying them that they were in violation of Proposition 65 for having failed to warn persons exposed to mercury from dental mercury used in fillings. The sixty-day notice period expired and the Attorney General did not file suit,[4] thus leaving ELF free to file its own suit seeking enforcement of Proposition 65. ELF negotiated a settlement with one manufacturer of dental mercury. The settlement required the manufacturer to provide a reproductive toxicity warning to dentists and to instruct that the warning be posted in the dental offices. Except under certain conditions, that have not arisen, the manufacturer

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4. The decision of the Attorney General not to file suit in response to a Sixty-Day Notice is not intended to be a reflection on the validity of the claim.

could continue to sell its product even if the dentists did not post the warning. A stipulated penalty was set at $328,000 but was reduced to zero and the manufacturer was instead required to pay $26,400 in attorneys' fees. *Environmental Law Foundation* v. *Jeneric-Pentron, Inc.*, No. 957039 (Cal. Super. Ct. San Francisco County, December 13, 1993) (stipulation for judgment).[5]

Before ELF could file suit, the Dental Parties sued the Attorney General of the State of California and the Director of the Office of Environmental Health Hazard Assessments ("OEHHA"), the state agency charged with drafting regulations for Proposition 65. The suit asked for declaratory relief and an injunction on the grounds that Proposition 65, as it applied to dental mercury, was preempted by the MDA. On August 24, 1994 the district court ruled that the prescription device labeling requirements of the MDA, 21 C.F.R. section 801.109, preempted the warning requirement of Proposition 65 as it applied to dental mercury and dental amalgam.

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5. Petitioners' description of the settlement (Petition at 22) is misleading. Petitioners neglected to inform the Court of the penalty reduction provision and the fact that, except under circumstances that have not yet arisen, the manufacturer can continue to sell dental mercury even if the dentists refuse to provide a warning to the dental patient.

The State Parties appealed the District Court's ruling. The Ninth Circuit, relying directly on this Court's decision in *Medtronic*, reversed the district court and held that the prescription device labeling requirements contained in 21 C.F.R. section 801.109 were not sufficiently specific to preempt state law. *Committee of Dental Amalgam Alloy Manufacturers and Distributors* v. *Stratton*, 92 F.3d 807, 812-13 (9th Cir. 1996). Again relying on this Court's decision in *Medtronic* and the regulation contained in 21 C.F.R. section 808.1(d), the Ninth Circuit also held that Proposition 65 was a state law of general applicability that was not enacted "with respect to" medical devices and therefore is not preempted by the MDA. *Dental Amalgam*, 92 F.3d at 813. Finally, the Ninth Circuit held that the FDA's failure to impose a federal reproductive toxicity warning requirement on dental mercury was not by itself preemptive. The Ninth Circuit concluded that, consistent with precedents of this Court and the decisions of numerous circuit courts, inaction by the FDA is not sufficient to trigger preemption under the MDA. *Id.*

The Ninth Circuit decision means that Proposition 65 can be enforced against the manufacturers of medical devices when the devices expose individuals to certain listed chemicals. The courts have not yet ruled on the question of whether a warning is required for dental mercury and what constitutes a clear and reasonable warning under the statute.

REASONS FOR DENYING THE WRIT

I.

THE NINTH CIRCUIT CORRECTLY DECIDED THE ISSUES IN THIS CASE BASED ON THIS COURT'S DECISION IN *MEDTRONIC*

In reaching its decision in *Dental Amalgam*, the Ninth Circuit had the benefit of this Court's decision in *Medtronic* v. *Lohr*, issued only one month prior to the Ninth Circuit decision. *Medtronic* interpreted the exact same federal preemption provision and regulations that are at issue here. The Ninth Circuit closely tracked both the reasoning and the holdings of *Medtronic* and its conclusions are consistent with this Court's opinion.

A. The *Dental Amalgam* Decision Follows this Court's Ruling in *Medtronic* that 21 C.F.R. Section 801.109 is not Sufficiently Specific to Preempt State Law Warning Requirements

At issue in the *Medtronic* case was the question of whether the prescription device labeling requirements contained in 21 C.F.R. section 801.109(b),(c) preempted state common law warning claims. 116 S.Ct. at 2256. This Court first held that:

> federal requirements must be "applicable to the device" in question, and, according to the regulations, preempt state law only if they are "specific counterpart regulations" or "specific" to a "particular device." The

> statute and regulations, therefore, require a careful comparison between the allegedly preempting federal requirement and the allegedly preempted state requirement to determine whether they fall within the intended preemptive scope of the statute and regulations.

Id. at 2257-58.

Noting that the statutory and regulatory language of the MDA does not necessarily preclude "general" federal requirements from ever preempting state requirements, 116 S.Ct. at 2257, the Court then went on to address the question of whether 21 C.F.R. section 801.109(b),(c) was a "specific counterpart regulation" that preempted state law. It concluded that it was not because it was too general:

> Such a comparison mandates a conclusion that the Lohrs' common-law claims are not preempted by the federal labeling and manufacturing requirements. The generality of those requirements make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers. Rather, the federal

> requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements.

Id. at 2258.

Here, the district court had determined that Proposition 65's warning requirement was preempted by the prescription device labeling requirement contained in 21 C.F.R. section 801.109. The Ninth Circuit quoted the above section of the *Medtronic* opinion and reversed the district court, holding that the prescription device labeling requirements were not "specific" enough to preempt state law. *Dental Amalgam*, 92 F.3d at 813.

The Dental Parties are therefore wrong when they assert that the Ninth Circuit has imposed a test for preemption that contradicts this Court's rulings and requires that a federal provision must apply exclusively to one type of medical device in order to preempt state law. (Petition at 18) The Ninth Circuit simply reiterated the direct holding of this Court concerning the preemptive effect of one particular federal requirement (21 C.F.R. section 801.109), and applied it to the facts of this case, holding that the same prescription device labeling requirements found by this Court to be too general to preempt state common law warning claims, were also too general to preempt a state law statutory warning requirement.

B. The *Dental Amalgam* Decision Follows This Court's Ruling in *Medtronic* that Certain State Laws of General Applicability are Not Preempted

Relying on the regulation contained in 21 C.F.R. section 808.1(d), this Court concluded that, while the statutory and regulatory language does not necessarily preclude general state requirements from ever being preempted, the state common law claims in *Medtronic* were not specifically developed "with respect to" medical devices and were not the kinds of requirements that Congress and the FDA intended to preempt. The Court went on to note that the common law claims, which included the failure to warn, were "no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a workforce." *Medtronic*, 116 S.Ct. at 2258.

Relying on *Medtronic*, the Ninth Circuit performed the "careful comparison between the allegedly preempting federal requirement and the allegedly preempted state requirement" (*Medtronic*, 116 S.Ct. at 2257-58) and concluded that Proposition 65, was not enacted "with respect to" medical devices and was not the kind of requirement that Congress and the FDA intended to preempt. Rather, Proposition 65 was directed at chemicals known to pose a health risk, and the state of California had not adopted any specific regulation or requirement that related to dental mercury or to the medical device industry. The court concluded therefore, that Proposition 65 was a statute of general applicability and was not preempted by the MDA because it was not the kind of requirement "that

Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements." *Dental Amalgam*, 92 F.3d at 813 (quoting *Medtronic*, 116 S.Ct. at 2257). The Ninth Circuit ruling therefore follows directly from and is consistent with *Medtronic*.

C. The *Dental Amalgam* Decision is Consistent with General Precedents of this Court and with the Decisions of Other Circuit Courts Holding that the FDA Cannot Preempt by Inaction

The Dental Parties next assert that this Court should grant the petition for writ of certiorari to address the question of whether the FDA can regulate by inaction -- *i.e.*, whether the FDA's failure to impose a requirement can preempt state law.[6]

The general question of when regulation can be inferred from inaction has already been answered by this Court. In *Puerto Rico Consumer Affairs Dept.* v. *Isla Petroleum Corp.*, 485 U.S. 495, 503 (1988) this Court held

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6. In presenting this question to the Court, petitioner represents that the FDA has "affirmatively rejected" a reproductive toxicity warning for dental mercury (Petition at 23). There is nothing in the record that demonstrates that the FDA has specifically considered and affirmatively rejected a reproductive toxicity warning for dental mercury. Furthermore, it is absolutely undisputed that the FDA has never promulgated a regulation prohibiting such a warning.

that "[t]here is no federal preemption *in vacuo*, without a constitutional text or a federal statute to assert it."

The federal statute and the regulations here make clear that Congress and the FDA did not anticipate regulation by inaction. The language of the preemption provision of the MDA states that preemption occurs only when there exists a "requirement applicable under this chapter to the device. . . . " 21 U.S.C. § 360k(a). In promulgating the regulation set forth in 21 C.F.R. section 808.1(d), the FDA specifically considered and rejected public comments arguing that, if no FDA requirement exists, any state requirement is "in addition to" an FDA requirement and is therefore preempted. 43 Fed.Reg. 19662 (1978). The FDA noted that "from a plain reading of section 521 of the act [360k] ***it is clear that the scope of preemption is limited to instances where there are specific FDA requirements applicable to a particular device or class of devices.***" *Id.* (Emphasis added.) The FDA went on to state unambiguously that:

> The language of section 521 of the act [360k] also does not support the argument that any State or local requirement is "in addition to" an FDA requirement if there is no FDA requirement. ***The phrase "or in addition to, any requirement applicable under this Act to the device" means that an FDA requirement must exist before preemption can occur.***

Id. (Emphasis added).

Discussion by the Commissioner of the FDA indicates further that the FDA does not intend to preempt by inaction. "Congress intended section 521(a) [360k] of the act to preempt only those different or

additional State and local requirements that relate to matters already governed by specific, established Federal requirements applicable to a specific device." 42 Fed.Reg. 9186 (Feb. 16, 1977). In a later discussion, the FDA provided a concrete example of the manner in which it envisioned preemption applying.

> For example, as noted in the recent regulation relating to professional and patient labeling and conditions for sale of hearing aids, State or local requirements that relate to such labeling requirements or conditions for sale *will be preempted by section 521(a) on the effective date of the hearing aid regulation. . . .*

42 Fed.Reg. 30384 (emphasis added). In other words, according to the FDA, until it acted to impose specific regulations on hearing aids, state regulation was not preempted.

Case law is unanimous in supporting the FDA's interpretation that preemption does not occur because of the agency's inaction. *See e.g.*, *King* v. *Collagen Corp.*, 983 F.2d 1130, 1134 (1st Cir. 1993), *cert. denied*, 510 U.S. 824 (1993) ("FDA regulations provide that preemption does not apply when the FDA has issued no regulations or other requirements specific to the particular device."); *Moore* v. *Kimberly-Clark Corp.*, 867 F.2d 243, 245 (5th Cir. 1989) (FDA requirement must exist before preemption occurs); *Lamontagne* v. *E. I. Du Pont de Nemours & Co.*, 834 F.Supp. 576, 585-86 (D.Conn. 1993), *aff'd.* 41 F.3d 846, 855 (2d Cir. 1994), (rejecting the

argument that state regulation was preempted because the FDA has chosen not to regulate).[7]

In *National Bank of Commerce* v. *Kimberly-Clark*, 38 F.3d 988, 997 (8th Cir. 1994) the tampon manufacturer defendant argued that, because the FDA had considered and rejected broader regulation of tampons, that decision by the FDA not to regulate preempted the plaintiff's claims. As noted by the court:

> Such a holding is precluded by the FDA's own regulations, but in addition, it would evince total disregard for the structure of our federal system. Absent clear statutory language to the contrary (or ambiguous statutory language accompanied by a reasonable agency interpretation to the contrary) it would be anomalous to suggest that the FDA may preempt all possible tort actions involving a particular product simply by placing it into a class or by imposing some general control.

Id.

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7. In *Lamontagne*, the court was faced with a regulation stating expressly that the FDA would not regulate manufacturers of raw materials because such regulation was not necessary to protect the public health. *See* 21 C.F.R. § 807.65. Despite this express determination, the court still found that the FDA refusal to regulate was not sufficient to preempt state law. *Lamontagne*, 834 F.Supp. at 585.

Thus, the Ninth Circuit decision here, refusing to find preemption by inaction, is consistent with the guidance provided by this Court in *Isla Petroleum* as well as with the decisions of the First, Second, Fifth and Eighth Circuits.

II.

THE *DENTAL AMALGAM* DECISION DOES NOT CONFLICT WITH THE DECISIONS IN OTHER CIRCUITS

In urging this Court to grant the petition for writ of certiorari, the Dental Parties assert that the standard for preemption in the Ninth Circuit conflicts with the standards in other circuits. The case law demonstrates however, that any conflicts exist only with cases that predate *Medtronic* and are therefore no longer necessarily good law.

This Court has provided significant guidance in *Medtronic* concerning preemption under the MDA. Apart from the Ninth Circuit, no other circuit court has had the opportunity to apply that guidance in the context of cases raising questions of preemption under the MDA. Thus, there is no conflict. Until a conflict arises, there is no reason for this Court to address issues that may well be resolved consistently at the circuit court level.

A. The *Dental Amalgam* Opinion is the Only Post-*Medtronic* Decision to Address the Question of Whether the Federal Prescription Device Labeling Requirements Preempt State Law

In its decision here, the Ninth Circuit, relying directly on *Medtronic*, ruled that the prescription device labeling requirements contained in 21 C.F.R. section 801.109 were not sufficiently specific to preempt Proposition 65's warning requirements. *Dental Amalgam*, 92 F.3d at 813.

Other than *Dental Amalgam*, there are no post-*Medtronic* cases that have dealt with the preemptive effect of these same requirements.[8] The only "conflict" asserted by the Dental Parties is based, not on the *Dental Amalgam* decision, not on the regulations contained in section 801.109 and not on a state statutory warning requirement, but rather on Ninth Circuit opinions in entirely different and earlier cases. One of those decisions, *Kennedy* v. *Collagen Corp.*, 67 F.3d 1453, 1458 (9th Cir. 1995) *cert. denied*, 116 S.Ct. 2579 (1996), dealt with the federal pre-market approval ("PMA") requirements (21 C.F.R. § 814.1) and their preemptive effect on state common law claims. The Kennedy court held that the PMA requirements did not preempt state law because they were not a "specific requirement applicable to a particular device." 67 F.3d at 1459. The Dental Parties claim that this reasoning conflicts with the decisions of the First, Third, Fifth and Eighth Circuits which have found that the PMA requirements are

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8. There are several earlier decisions that found that 21 CFR section 801.109 did preempt state common law warning claims. *See, e.g.*, *Mendes* v. *Medtronic*, 18 F.3d 13, 18 (1st Cir. 1994); *Reeves* v. *Acromed Corp.*, 44 F.3d 300, 305 (5th Cir.), *cert. denied*, 115 S.Ct. 2251 (1995). None of these cases is good law after this Court's decision in *Medtronic*.

sufficiently specific to preempt state common law. (Petition at 19).

Whether a conflict exists or not, it exists in an entirely different, pre-*Medtronic* case, dealing with a different federal requirement, and different state requirements.[9] The question whether a specific federal requirement preempts state law must be addressed on a case by case basis by comparing the federal and state requirements at issue, *Medtronic*, 116 S.Ct. at 2257-58. The *Dental Amalgam* case, involving a device that did not go through the pre-market approval process, is simply not an appropriate vehicle with which to address the questions raised by *Kennedy*.[10]

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9. The second decision on which the Dental Parties based their conflict argument is *Anguiano* v. *E.I. DuPont de Nemours & Co.*, 44 F.3d 806, (9th Cir. 1995). *Anguiano*, however, is consistent with this Court's ruling in *Medtronic*. In *Anguiano*, the device at issue, a temporomandibular joint (TMJ), was subject only to the identification and classification regulations that are used to classify all medical devices. While the court did not discuss the prescription device labeling requirements contained in 21 C.F.R. section 801.109, those are the only labeling requirements that would have been applicable to the TMJ. Thus, the Ninth Circuit's ruling in *Anguiano*, 44 F.3d at 809-10, that the federal requirements were not sufficiently specific to preempt state common law claims, is consistent with the *Medtronic* opinion.

10. Furthermore, this Court denied certiorari in *Kennedy* only days after it decided *Medtronic*. It simultaneously vacated and remanded at least one circuit court decision that raises the exact question presented by

B. The Ninth Circuit is the Only Circuit Court to Have Addressed the Question of Whether a State Statute is of General Applicability and Therefore Not Preempted by the MDA

In *Medtronic*, this Court provided significant guidance concerning when state requirements are requirements of general applicability, not specifically developed with respect to medical devices and therefore not preempted. The Court has made clear that certain general state requirements are not the kinds of requirements that Congress and the FDA feared would impede the federal regulators from enforcing federal requirements and are therefore not a threat to federal requirements. 116 S.Ct. at 2258.

The *Dental Amalgam* opinion is the only case to date to have applied the *Medtronic* guidance in determining that a state requirement is of general applicability and is not intended to be preempted by federal law. This decision cannot conflict with any of the cases cited by the Dental Parties, all of which predate *Medtronic* and all of which deal with state common law requirements.[11/]

Kennedy, i.e., whether the PMA process is a specific requirement that preempts state common law claims. *See Mitchell* v. *Collagen Corp.*, 67 F.3d 1268, 1279 (7th Cir. 1995), *vacated and remanded* 116 S.Ct. 2576 (1996). If the *Mitchell* decision on remand continues to presents a direct conflict with *Kennedy*, the Court will have an appropriate vehicle in which to resolve that conflict.

11. *See Michael* v. *Shiley, Inc.*, 46 F.3d 1316 (3d Cir.), *cert. denied*, 116 S.Ct. 67 (1995); *Gile* v. *Optical*

Recognizing the absence of a direct conflict, the Dental Parties again shift the focus of their argument from the *Dental Amalgam* decision to the *Kennedy* decision. (Petition at 15) The pre-*Medtronic Kennedy* opinion dealt with preemption of common law tort claims and concluded that, if a state common law requirement is not specifically directed at medical devices, but affects such devices in the same manner as it affects all other products, it is not preempted. *Kennedy*, 67 F.3d at 1462. While the Ninth Circuit *Kennedy* opinion did conflict with pre-*Medtronic* decisions in other circuits, *see* 67 F.3d at 1461, n.3 (Reinhardt, J. concurring), it is consistent with this Court's decision in *Medtronic* that the particular common law claims at issue were not specifically developed "with respect to" medical devices and were therefore not preempted. 116 S.Ct. at 2258. Furthermore, this Court specifically chose to address any existing conflict by denying certiorari in *Kennedy* (116 S.Ct. 2579), and vacating and remanding a number of decisions that presented a potential conflict with *Kennedy*.[12/]

Radiation Corp., 22 F.3d 540, 543 n.2 (3d Cir.), *cert. denied*, 115 S.Ct. 429 (1994); *Talbott* v. *C.R. Bard, Inc.*, 63 F.3d 25, 29 (1st Cir. 1995), *cert. dismissed*, 116 S.Ct. 1892 (1996); *Becker* v. *Optical Radiation Corp.*, 66 F.3d 18, 20 n.2, 20-21 (2d Cir. 1995); *Stamps* v. *Collagen Corp.*, 984 F.2d 1416, 1421 (5th Cir.), *cert. denied*, 510 U.S. 824 (1993); *Slater* v. *Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 505 U.S. 917 (1992); *Martello* v. *Ciba Vision Corp.*, 42 F.3d 1167, 1169 (8th Cir. 1994); *Duncan* v. *Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994).

12. *English* v. *Mentor Corp.*, 67 F.3d 477 (3d Cir. 1995), *vacated and remanded*, 116 S.Ct. 2575 (1996);

Thus, any conflict in the law concerning preemption of common law tort claims exists not in the *Dental Amalgam* decision, but in other, pre-*Medtronic* decisions and should be resolved only after the circuit courts have had an opportunity to reevaluate their positions in light of this Court's ruling in *Medtronic*. Since the Court has remanded a number of circuit court decisions for further considerations in light of *Medtronic*, it will have ample opportunity to resolve any conflicts that remain. Furthermore, consistent with this Court's ruling that preemption analysis demands a careful comparison between the federal and state requirements at issue, 116 S.Ct. at 2257-58, any conflicts concerning preemption of particular common law claims can only be resolved in the context of cases raising the same or similar common law claims. The *Dental Amalgam* case is simply not an appropriate vehicle in which to resolve these conflicts.

In summary, this Court has now provided significant guidance concerning the preemption of state law requirements. That guidance was specifically applied to the facts of this case by the Ninth Circuit and will be applied to different facts by different circuits. Until the

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Duvall v. *Bristol-Myers Squibb Co.*, 65 F.3d 392 (4th Cir. 1995), *vacated and remanded*, 116 S.Ct. 2575 (1996); *Bingham* v. *Mentor Corp.*, 89 F.3d 203 (5th Cir.), *vacated and remanded*, 116 S.Ct. 2577 (1996); *Feldt* v. *Mentor Corp.*, 61 F.3d 431 (5th Cir. 1995), *vacated and remanded*, 116 S.Ct. 2575 (1996); *Martin* v. *Telectronics Pacing Sys., Inc.*, 70 F.3d 39 (6th Cir. 1995), *vacated and remanded*, 116 S.Ct. 2576 (1996); *Mitchell* v. *Collagen Corp.*, 67 F.3d 1268 (7th Cir. 1995), *vacated and remanded*, 116 S.Ct. 2576 (1996).

circuit courts have had an opportunity to consider and apply the *Medtronic* decision to their own cases, there is no conflict for this Court to resolve.

III.

THE SCOPE OF FDA AUTHORITY UNDER THE MDA IS WELL DEFINED AND THERE IS NO NEED FOR THIS COURT TO ADDRESS THE EXTENT OF THAT AUTHORITY

In a final argument, the Dental Parties attempt to present the Court with a question they term one of "federalism" -- whether the FDA can regulate by inaction -- and suggest that the Court grant certiorari in order to define the relationship between state and federal power over medical devices. The question of FDA regulation by inaction, however, does not raise an issue of federalism, but rather one of statutory interpretation. "There is no federal preemption *in vacuo*, without a constitutional text or a federal statute to assert it." *Isla Petroleum*, 485 U.S. at 503.

Here, the scope of the FDA's authority to regulate is clear from the statute and, pursuant to 21 U.S.C. sections 360h(a) and 371(a) and 21 C.F.R. section 895.25, the FDA has the absolute authority to promulgate a regulation prohibiting the use of a reproductive toxicity warning for dental mercury. It has not done so. Furthermore, the language of the MDA, the provisions of the regulations and the comments of the FDA make clear that neither Congress nor the FDA intends that the Agency regulate by inaction. *See* 21 U.S.C. § 360k(a), 21 C.F.R. § 808.1(d), 43 Fed. Reg. 19662, 42 Fed. Reg. 9186, 42 Fed. Reg. 30384. *See also King*, 983 F.2d at 1130; *Moore*, 867 F.2d at 245;

Lamontagne, 834 F.Supp. at 585-86, *aff'd.* 41 F.3d at 855; *National Bank of Commerce*, 38 F.3d at 997.

Finally, contrary to the representations of the Dental Parties, the *Dental Amalgam* decision, permitting the State to seek to enforce a warning requirement even though federal law does not impose the requirement is neither unusual nor extraordinary. It is precisely what the preemption provisions of the MDA anticipate. *See Medtronic*, 116 S.Ct. at 2256-57 (permitting state common law failure to warn and negligent manufacturing claims.

Nor is it unusual that the Proposition 65 warning requirement may be enforced pursuant to a citizen suit. Citizen suit provisions are a staple of federal statutes and have long been recognized as a legitimate enforcement mechanism in federal law. *See* Clean Water Act 33 U.S.C. § 1365(a)(1).[13]

Finally, in an argument never addressed to the courts below, the Dental Parties represent that the warning requirement of Proposition 65 violates federal law. (Petition at 26) This argument is not only improper because it was not raised below, it is absolutely incorrect. In making this claim, the Dental Parties quote from a report of the Department of Health and Human Services, stating that the FDA could take action to prevent individual dentists from claiming that dental amalgams are toxic to humans or causative agents for

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13. While Petitioners are correct that the Attorney General has criticized certain citizen suits brought by irresponsible private groups, he has never indicated that he believed that the Environmental Law Foundation fell into that category.

diseases. *Dental Amalgam: A Scientific Review* at VI-5 ("*Dental Amalgam Report*") (Petition at 26). The report, "A Scientific Review and Recommended Public Health Strategy for Research, Education and Regulation," was directed at the alleged practice of certain dentists in promoting amalgam removal and replacement by other materials. The *Dental Amalgam Report*, however, can hardly be taken as an indication that a Proposition 65 warning is illegal under federal law. First, the report was issued by the United States Department of Health and Human Services, not by the FDA and is not a definitive statement of the scope of FDA authority. Second, the Report, in the next sentence not quoted by the Dental Parties, goes on to indicate that any question of improper activity by dentists is better handled by the states through licensing and regulating bodies, rather than by the FDA. Third, the FDA has always recognized that "mercury is a poison," 52 Fed.Reg. 30089, and fourth, and finally, while the FDA has the authority to prohibit a reproductive toxicity warning, it has not done so. Thus, federal law simply does not prohibit either manufacturers of dental mercury or dentists from providing an appropriate Proposition 65 warning pursuant to state law.

CONCLUSION

In the *Medtronic* decision, this Court has provided significant clarification to an area of law that was in considerable disarray. The *Medtronic* decision addressed the same statute and the same federal requirements that are at issue here. The Ninth Circuit, which simply followed this Court's reasoning and conclusions, is the first circuit court to apply the *Medtronic* reasoning to the facts of a specific case and to perform the careful comparison between federal and

state requirements that is mandated by this Court. Until other circuit courts have had the same opportunity to apply *Medtronic*, there is no conflict that justifies this Court granting the petition for writ of certiorari.

The Court should deny the petition for writ of certiorari.

Respectfully submitted,

DANIEL E. LUNGREN
Attorney General
RODERICK E. WALSTON
Chief Assistant Attorney General
THEODORA BERGER
Assistant Attorney General
CRAIG C. THOMPSON
EDWARD G. WEIL
SUSAN S. FIERING*
Deputy Attorneys General
(*Counsel of Record)

Attorneys for Respondents

December 4, 1996.

APPENDIX TO THE OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

implementing regulations included any requirement concerning the advertising of hearing aids, West's Ann. Health & Safety Code, § 26463(m) making it unlawful for any person to advertise any device represented to have any effect on diseases or disorders of the ear or auditory apparatus, including hearing loss, was not preempted by federal law. Kievlan v. Dahlberg Electronics, Cal.App. 1 Dist.1978, 144 Cal.Rptr. 585, 78 Cal.App.3d 961, appeal dismissed 99 S.Ct. 1487, 440 U.S. 951, 59 L.Ed.2d 765.

3. Restrictive devices

In establishing what medical devices are "restrictive devices" under this section, the Secretary is not forbidden from using language approaching the generality of this section if, after appropriate rule-making procedures, he should find it impracticable to be more specific, and it was not intended that he make specific determinations with respect to each device, with the consequence that a new device would not be "restricted" until a special rule had been developed for it. Becton, Dickinson and Co. v. Food and Drug Administration, C.A.2 (N.Y.) 1978, 589 F.2d 1175.

Notice published by the Secretary in the federal register stating that "restricted devices" now include all "prescription devices" as defined in previously promulgated regulations was not sufficient regulation under this section to satisfy requirement that the Secretary may by regulation require that a device be restricted in sale, distribution or use if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. Becton, Dickinson and Co. v. Food and Drug Administration, C.A.2 (N.Y.) 1978, 589 F.2d 1175.

Medical Device Amendments (MDA) to Food, Drug & Cosmetic Act did not preempt state law causes of action based upon strict liability, negligence, and breach of implied warranty, of individual allegedly injured by defective prosthetic knee device, as those causes of action were requirements of general applicability rather than state laws enacted specifically with regard to "device intended for human use," and state law liability was specifically contemplated by MDA. Mulligan v. Pfizer Inc., S.D.Ohio 1994, 850 F.Supp. 633.

4. Mandatory nature of section

Subsec. (h)(2) of this section establishing scheme under which Administration was required to make available to public "a detailed summary of information respecting the safety and effectiveness of a device which information was submitted to the [agency] and which was the basis for" specified orders or was submitted to advisory committee and formed basis for its recommendations to Administration did not specifically prohibit disclosure of records produced during ongoing clinical studies of safety and efficacy of intraocular lenses as required under exemption provisions of section 552(b)(3) of Title 5 allowing agencies to withhold records that are "specifically exempted from disclosure by statute." Public Citizen Health Research Group v. Food and Drug Admin., C.A.D.C.1983, 704 F.2d 1280, 227 U.S.App.D.C. 151.

5. Custom device

Food and Drug Administration acted reasonably in refusing to accord "custom-device" status to rigid gas permeable contact lenses within meaning of statute [21 U.S.C.A. § 360j(b)] which provides exemption for custom devices from classification scheme of Medical Device Amendments of 1976 [21 U.S.C.A. §§ 360c–360k]. Contact Lens Mfrs. Ass'n v. Food & Drug Admin. Dept. of Health and Human Services, C.A.D.C.1985, 766 F.2d 592, 247 U.S.App.D.C. 102, certiorari denied 106 S.Ct. 810, 474 U.S. 1062, 88 L.Ed.2d 784.

6. Good manufacturing practice

Manufacturer of latex surgical gloves violated finished device testing requirements of good manufacturing practice regulations under Federal Food, Drug, and Cosmetic Act by failing to adhere to any recognized glove testing standard. U.S. v. 789 Cases, More or Less, of Latex Surgeons' Gloves, an Article of Device, D.Puerto Rico 1992, 799 F.Supp. 1275.

Compliance office of division of compliance programs of Food and Drug Administration could not bypass process for establishing good manufacturing practice and was required to comply with process in order to require manufacturers of plated culture media to meet sterility assurance level of 0.1%. U.S. v. Bioclinical Systems, Inc., D.Md.1987, 666 F.Supp. 82.

§ 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such

regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

(June 25, 1938, c. 675, § 521, as added May 28, 1976, Pub.L. 94-295, § 2, 90 Stat. 574.)

HISTORICAL AND STATUTORY NOTES

Change of Name

The Department of Health, Education, and Welfare was redesignated the Department of Health and Human Services, and the Secretary of Health, Education, and Welfare or any other official of the Department of Health, Education and Welfare was redesignated the Secretary or official, as appropriate, of Health and Human Services, with any reference to the Department of Health, Education, and Welfare, the Secretary of Health, Education, and Welfare, or any official of the Department of Health, Education, and Welfare, in any law, rule, regulation, certificate, directive, instruction, or other official paper in force on the effective date of Pub.L. 96-88, as prescribed by section 601 of Pub.L. 96-88, Title VI, Oct. 17, 1979, 93 Stat. 696, set out as a note under section 3401 of Title 20, Education, deemed to refer and apply to the Department of Health and Human Services or the Secretary of Health and Human Services, respectively, except to the extent such reference is to a function or office transferred to the Secretary of Education or the Department of Education under Pub.L. 96-88, Title III, §§ 301 to 307, Oct. 17, 1979, 93 Stat. 677 to 681. See section 3441 to 3447 and 3508 of Title 20.

Legislative History

For legislative history and purpose of Pub.L. 94-295, see 1976 U.S. Code Cong. and Adm. News, p. 1070.

CODE OF FEDERAL REGULATIONS

Exemption from federal preemption, see 21 CFR 808.1 et seq.

LAW REVIEW COMMENTARIES

Preemption of state tort claims under the medical device amendments. Stephen D. Harris, 24 Colo.Law. 2217 (1996).

Who should bear the burden of experimental medical device testing: The preemptive scope of the medical device amendments under *Slater v. Optical Radiation Corp.* 43 DePaul L.Rev. 963 (1994).

LIBRARY REFERENCES

Food ⇐1 et seq.
C.J.S. Food § 4(1) et seq.

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1. Requirement applicable to the device

Preemption of state requirements for products by Medical Device Amendments to Food, Drug and Cosmetic Act occurs when either general or specific requirements of Amendments apply to product. English v. Mentor Corp., C.A.3 (Pa.) 1995, 67 F.3d 477, petition for certiorari filed.

Good manufacturing practice requirements applicable to penile implant, which was Class III medical device under Medical Device Amendments to Federal Food, Drug, and Cosmetic Act (MDA), which included standards for production facilities, quality assurance, monitoring of package labels, and device failure reporting requirements, and labeling requirements, which mandated content of labels and prominence of required statements, were "requirements" and give rise to preemption under MDA of state law claims based on failure to comply with requirements. Duvall v. Bristol-Myers-Squibb Co., C.A.4 (Md.) 1996, 65 F.3d 392, petition for certiorari filed.

Food and Drug Administration (FDA) regulation providing that state and local requirements for medical devices were preempted by Medical Device Amendments (MDA) only when FDA has established specific counterpart regulations or there were other specific regulations applicable to particular device under FDA. did not limit preemption to cases of regulations covering specific device; preemption could be found if regulations covered particular process, procedure or device. Lohr v. Medtronic, Inc., C.A.11 (Fla.) 1996, 56 F.3d 1335, rehearing and suggestion for rehearing en banc denied, certiorari granted.

(f) Statement of reasons

To facilitate judicial review under this section or under any other provision of law of a regulation or order issued under section 360c, 360d, 360e, 360f, 360h, 360i, 360j, or 360k of this title each such regulation or order shall contain a statement of the reasons for its issuance and the basis, in the record of the proceedings held in connection with its issuance, for its issuance.

(June 25, 1938, c. 675, § 517, as added May 28, 1976, Pub.L. 94-295, § 2, 90 Stat. 560, and amended Nov. 28, 1990, Pub.L. 101-629, § 13, 104 Stat. 4524; June 16, 1992, Pub.L. 102-300, § 6(f), 106 Stat. 240.)

HISTORICAL AND STATUTORY NOTES

1992 Amendments

Subsec. (a)(10). Pub.L. 102-300, § 6(f), substituted "section 360j(h)(4)(B)" for "section 360j(c)(4)(B)".

1990 Amendment

Subsec. (a)(8)-(10). Pub.L. 101-629, § 13, added pars. (8) to (10).

Change of Name

The Department of Health, Education, and Welfare was redesignated the Department of Health and Human Services, and the Secretary of Health, Education, and Welfare or any other official of the Department of Health, Education and Welfare was redesignated the Secretary or official, as appropriate, of Health and Human Services, with any reference to the Department of Health, Education, and Welfare, the Secretary of Health, Education, and Welfare, or any official of the Department of Health, Education, and Welfare, in any law, rule, regulation, certificate, directive, instruction, or other official paper in force on the effective date of Pub.L. 96-88, as prescribed by section 601 of Pub.L. 96-88, Title VI, Oct. 17, 1979, 93 Stat. 696, set out as a note under section 3401 of Title 20, Education, deemed to refer and apply to the Department of Health and Human Services or the Secretary of Health and Human Services, respectively, except to the extent such reference is to a function or office transferred to the Secretary of Education or the Department of Education under Pub.L. 96-88, Title III, §§ 301 to 307, Oct. 17, 1979, 93 Stat. 677 to 681. See section 3441 to 3447 and 3508 of Title 20.

Legislative History

For legislative history and purpose of Pub.L. 94-295, see 1976 U.S. Code Cong. and Adm. News, p. 1070. See, also, Pub.L. 101-629, 1990 U.S. Code Cong. and Adm. News, p. 6305.

LIBRARY REFERENCES

Food ⇐22.
C.J.S. Food § 48.

§ 360h. Notification and other remedies

(a) Notification

If the Secretary determines that—

(1) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health, and

(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk,

the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all health professionals who prescribe or use the device and to any other person (including manufacturers, importers, distributors, retailers, and device users) who should properly receive such notification in order to eliminate such risk. An order under this subsection shall require that the individuals subject to the risk with respect to which the order is to be issued be included in the persons to be notified of the risk unless the Secretary determines that notice to such individuals would present a greater danger to the health of such individuals than no such notification. If the Secretary makes such a determination with respect to such individuals, the order shall require that the health professionals who prescribe or use the device provide for the notification of the individuals whom the health professionals treated with the device of the risk presented by the device and of any action which may be taken by or on behalf of such individuals to eliminate or reduce such risk. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

Department of Agriculture to the Federal Security Agency, to be administered under the direction and supervision of the Federal Security Administrator, by 1940 Reorg.Plan No. IV, set out in the Appendix to Title 5.

§ 364. Repealed. Pub.L. 86-618, Title I, § 103(a) (3), July 12, 1960, 74 Stat. 398

Historical Note

Section, Act June 25, 1938, c. 675, § 604, 52 Stat. 1055, required the Secretary to promulgate regulations for the listing of coal-tar colors for cosmetics and is covered by section 376 of this title.

Effective Date of Repeal. Repeal of section effective, subject to the provisions of section 208 of Pub.L. 86-618, on July 12, 1960, see section 202 of Pub.L. 86-618, set out as a note under section 376 of this title.

SUBCHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

§ 371. Regulations and hearings—Authority to promulgate regulations

(a) The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

Regulations for imports and exports

(b) The Secretary of the Treasury and the Secretary of Health, Education, and Welfare shall jointly prescribe regulations for the efficient enforcement of the provisions of section 381 of this title, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Health, Education, and Welfare shall determine.

Conduct of hearings

(c) Hearings authorized or required by this chapter shall be conducted by the Secretary of Health, Education, and Welfare or such officer or employee as he may designate for the purpose.

Effectiveness of definitions and standards of identity

(d) The definitions and standards of identity promulgated in accordance with the provisions of this chapter shall be effective for the purposes of the enforcement of this chapter, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

Procedure for establishment

(e) (1) Any action for the issuance, amendment, or repeal of any regulation under section 341, 343(j), 344(a), 346, 351(b), or 352(d) or

(2) That the requirement is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of any applicable requirement under the act.

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

(3) Section 521(a) does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of medicine, dentistry, optometry, pharmacy, nursing, podiatry, or any other of the healing arts or allied medical sciences or related professions or occupations that administer, dispense, or sell devices. However, regulations issued under section 520(e) or (g) of the act may impose restrictions on the sale, distribution, or use of a device beyond those prescribed in State or local requirements. If there is a conflict between such restrictions and State or local requirements, the Federal regulations shall prevail.

(4) Section 521(a) does not preempt specifications in contracts entered into by States or localities for procurement of devices.

(5) Section 521(a) does not preempt criteria for payment of State or local obligations under Medicaid and similar Federal, State or local health-care programs.

(6)(i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and others, and prohibition of manufacture of devices in unlicensed establishments. However, Federal regulations issued under sections 519 and 520(f) of the act may impose requirements for records and reports and good manufacturing practices beyond those prescribed in State or local requirements. If there is a conflict between such regulations and State or local requirements, the Federal regulations shall prevail.

(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act. In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

(7) Section 521(a) does not preempt State or local provisions respecting delegations of authority and related administrative matters relating to devices.

(8) Section 521(a) does not preempt a State or local requirement whose sole purpose is raising revenue or charging fees for services, registration, or regulatory programs.

(9) Section 521(a) does not preempt State or local requirements of the types that have been developed under the Atomic Energy act of 1954 (42 U.S.C. 2011 note), as amended, the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602 (42 U.S.C. 263b et seq.)) and other Federal statutes, until such time as the Food and Drug Administration issues specific requirements under the Federal Food, Drug, and Cosmetic Act applicable to these types of devices.

(e) It is the responsibility of the Food and Drug Administration, subject to review by Federal courts, to determine whether a State or local requirement is equal to, or substantially identical to, requirements imposed by or under the act, or is different from, or in addition to, such requirements, in accordance with the procedures provided by this part. However, it is the responsibility of States and political subdivisions to determine initially whether to seek exemptions from preemption. Any State or political subdivision whose requirements relating to devices are preempted by section 521(a) may petition the Commissioner of Food and Drugs for exemption from preemption, in accordance with the procedures provided by this part.

(f) The Federal requirement with respect to a device applies whether or not a corresponding State or local requirement is preempted or exempted from preemption. As a result, if a State or local requirement that the Food and Drug Administration has exempted from preemption is not as broad in its application as the Federal requirement, the Federal requirement applies to all circumstances not covered by the State or local requirement.

[43 FR 18665, May 2, 1978, as amended at 45 FR 67336, Oct. 10, 1980]

§ 808.3 Definitions.

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) *Compelling local conditions* includes any factors, considerations, or circumstances prevailing in, or characteristic of, the geographic area or population of the State or political subdivision that justify exemption from preemption.

(c) *More stringent* refers to a requirement of greater restrictiveness or one that is expected to afford to those who may be exposed to a risk of injury from a device a higher degree of protection than is afforded by a requirement applicable to the device under the act.

(d) *Political subdivision* or *locality* means any lawfully established local governmental unit within a State which unit has the authority to establish or continue in effect any requirement having the force and effect of law with respect to a device intended for human use.

(e) *State* means a State, American Samoa, the Canal Zone, the Commonwealth of Puerto Rico, the District of Columbia, Guam, Johnston Island, Kingman Reef, Midway Island, the Trust Territory of the Pacific Islands, the Virgin Islands, and Wake Island.

(f) *Substantially identical to* refers to the fact that a State or local requirement does not significantly differ in effect from a Federal requirement.

§ 808.5 Advisory opinions.

(a) Any State, political subdivision; or other interested person may request an advisory opinion from the Commissioner with respect to any general matter concerning preemption of State or local device requirements or with respect to whether the Food and Drug Administration regards particular State or local requirements, or proposed requirements, as preempted.

(1) Such an advisory opinion may be requested and may be granted in accordance with § 10.85 of this chapter.

(2) The Food and Drug Administration, in its discretion and after consultation with the State or political subdivision, may treat a request by a State or political subdivision for an advisory opinion as an application for exemption from preemption under § 808.20.

(b) The Commissioner may issue an advisory opinion relating to a State or local requirement on his own initiative when he makes one of the following determinations:

(1) A requirement with respect to a device for which an application for exemption from preemption has been submitted under § 808.20 is not preempted by section 521(a) of the act because it

practice or by unavoidable deviations in good manufacturing practice will be recognized. Variations from stated quantity of contents shall not be unreasonably large.

Subpart D—Exemptions From Adequate Directions for Use

§ 801.109 Prescription devices.

A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

(a) The device is:

(1)(i) In the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or

(ii) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device; and

(2) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

(b) The label of the device, other than surgical instruments, bears:

(1) The statement "Caution: Federal law restricts this device to sale by or on the order of a ####", the blank to be filled with the word "physician", "dentist", "veterinarian", or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

(2) The method of its application or use.

(c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented: *Provided, however,* That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

(d) Any labeling, as defined in section 201(m) of the act, whether or not it is on or within a package from which the device is to be dispensed, distributed by or on behalf of the manufacturer, packer, or distributor of the device, that furnishes or purports to furnish information for use of the device contains adequate information for such use, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented. This information will not be required on so-called reminder—piece labeling which calls attention to the name of the device but does not include indications or other use information.

(e) All labeling, except labels and cartons, bearing information for use of the device also bears the date of the issuance or the date of the latest revision of such labeling.

§ 801.110 Retail exemption for prescription devices.

A device subject to § 801.109 shall be exempt at the time of delivery to the ultimate purchaser or user from section 502(f)(1) of the act if it is delivered by a licensed practitioner in the course of his professional practice or upon a prescription or other order lawfully issued in the course of his professional practice, with labeling bearing the name and address of such licensed practitioner and the directions for use and cautionary statements, if any, contained in such order.

§ 895.22 Submission of data and information by the manufacturer, distributor, or importer.

(a) A manufacturer, distributor, or importer of a device may be required to submit to the Food and Drug Administration all relevant and available data and information to enable the Commissioner to determine whether the device presents substantial deception, unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals. The data and information required by the Commissioner may include scientific or test data, reports, records, or other information, including data and information on whether the device is safe and effective for its intended use or when used as directed, whether the device performs according to the claims made for the device, and information on adulteration or misbranding. Any relevant information that is voluntarily submitted will also be reviewed.

(b) A manufacturer, distributor, or importer of a device required to submit data and information as provided in paragraph (a) of this section will be notified in writing by the Food and Drug Administration that such data and information shall be submitted. The written notification will advise the manufacturer, distributor, or importer of the device that the purpose for the request is to enable the Commissioner to determine whether any of the conditions listed in paragraph (a) of this section or §895.30(a)(1) exists with respect to the device such that a proceeding should be initiated to make the device a banned device. When the required data and information can be identified by the Food and Drug Administration at the time of the notification, the agency will provide such identification to the manufacturer, distributor, or importer of the device.

(c) The required data and information shall be submitted to the Food and Drug Administration no more than 30 days after the date of receipt of the request, unless the Commissioner determines that the data and information shall be submitted by some other date and so informs the manufacturer, distributor, or importer, in which case the data and information shall be submitted on the date specified by the Commissioner.

(d) If the data or information submitted to the Food and Drug Administration is sufficient to persuade the Commissioner that the deception or risk of illness or injury or the danger to the health of individuals presented by a device could be corrected or eliminated by labeling or change in labeling, or change in advertising if the device is a restricted device, the Commissioner will proceed in accordance with §895.25.

(e) If the data or information submitted to the Food and Drug Administration is insufficient to show that the device does not present a substantial deception or an unreasonable and substantial risk of illness or injury, or an unreasonable, direct, and substantial danger to the health of individuals, or if the manufacturer, distributor, or importer fails to submit the required information, the Commissioner may rely upon this insufficiency or failure to submit the required information in considering whether to initiate a proceeding to make the device a banned device under §895.21(d) and, when appropriate, to establish a special effective date in accordance with §895.30. The Commissioner may also initiate other regulatory action as provided in the act or this chapter.

§ 895.25 Labeling.

(a) If the Commissioner determines that the substantial deception or unreasonable and substantial risk of illness or injury or the unreasonable, direct, and substantial danger to the health of individuals presented by a device can be corrected or eliminated by labeling or a change in labeling, or change in advertising if the device is a restricted device, the Commissioner will provide written notice to the manufacturer, distributor, importer, or any other person(s) responsible for the labeling or advertising of the device specifying:

(1) The deception or risk of illness or injury or the danger to the health of individuals,

(2) The labeling or change in labeling, or change in advertising if the device is a restricted device, necessary to correct the deception or eliminate or reduce such risk or danger, and

(3) The period of time within which the labeling, change in labeling, or change in advertising must be accomplished.

(b) In specifying the labeling or change in labeling or change in advertising to correct the deception or to eliminate or reduce the risk of illness or injury or the danger to the health of individuals, the Commissioner may require the manufacturer, distributor, importer, or any other person(s) responsible for the labeling or advertising of the device to include in labeling for the device, and in advertising if the device is a restricted device, a statement, notice, or warning. Such statement, notice, or warning shall be in the manner and form prescribed by the Commissioner and shall identify the deception or risk of illness or injury or the unreasonable, direct, and substantial danger to the health of individuals associated with the device as previously labeled. Such statement, notice, or warning shall be used in the labeling and advertising of the device for a time period specified by the Commissioner on the basis of the degree of deception, risk of illness or injury, or danger to health; the frequency of sale of the device; the length of time the device has been on the market; the intended uses of the device; the method of its use; and any other factors that the Commissioner considers pertinent.

(c) The Commissioner will allow a manufacturer, distributor, importer, or any other person(s) responsible for the labeling or advertising of the device a reasonable time, considering the deception or risk of illness or injury or the danger to the health of individuals presented by the device, within which to accomplish the required labeling, change in labeling, and, if the device is a restricted device, any change in advertising. The Commissioner may, however, request that no additional devices be introduced into commerce until the labeling or change in labeling, or change in advertising is accomplished by the manufacturer, distributor, importer, or other person(s) responsible for the labeling or advertising of the device.

(d) If such voluntary action is not taken, the Commissioner may take action under other sections of the act to prevent the introduction of the devices into commerce. The Commissioner may consider the failure of a manufacturer, distributor, importer, or any other person(s) responsible for the labeling or advertising of the device to accomplish the required labeling or change in labeling, or change in advertising in accordance with this section as a basis for initiating a proceeding to make a device a banned device in accordance with § 895.21(d) and when appropriate to establish a special effective date in accordance with § 895.30.

§ 895.30 Special effective date.

(a) The Commissioner may declare a proposed regulation under § 895.21(d) to be effective upon its publication in the FEDERAL REGISTER and until the effective date of any final action taken respecting the regulation if:

(1) The Commissioner determines, on the basis of all available data and information, that the deception or risk of illness or injury associated with use of the device that is subject to the regulation presents an unreasonable, direct, and substantial danger to the health of individuals, and

(2) Before the date of the publication of such regulation, the Commissioner notifies the domestic manufacturer and importer, if any, of the device that the regulation is to be made so effective. If necessary, the Commissioner may also notify the distributor or any other responsible person(s). In addition, the Commissioner will attempt to notify any foreign manufacturer when the name and address of the foreign manufacturer are readily available.

(b) This procedure may be used when the Commissioner determines that the potential or actual injury involved is a serious one that the Commissioner believes will endanger the health of individuals who have been, or will be, exposed to the device. In assessing the degree of danger, the Commissioner need not find that the danger is immediate, and it shall be sufficient for the Commissioner to determine that the danger may involve a serious long-term risk.

(c) If the Commissioner makes a proposed regulation effective in accordance with this section, the Commissioner will, as expeditiously as possible, give interested persons prompt

"(d) To shift the cost of hazardous waste cleanups more onto offenders and less onto law-abiding taxpayers.

"The people hereby enact the provisions of this initiative in furtherance of these rights."

Sections 6, 7 and 8 of Initiative Measure, Nov. 4, 1986, provide:

"Sec. 6. If any provision of this initiative or the application thereof is held invalid, that invalidity shall not affect other provisions or applications of the initiative which can be given effect without the invalid provision or application, and to this end the provisions of this initiative are severable.

"Sec. 7. To further its purposes this initiative may be amended by statute, passed in each house by a two-thirds vote.

"Sec. 8. This initiative shall take effect on January 1, 1987."

Amendment of this section by Stats.1990, c. 407 (Prop. 141) was rejected at the Nov. 6, 1990, general election.

Law Review Commentaries

California's toxics initiative: Making it work. Note, 39 Hast.L.J. 1195 (1988).

Problems with Prop. 65: Will California's toxics initiative hold water? James Dragna, 10 L.A.Law. 18 (April 1987).

§ 25249.6. Required warning before exposure to chemicals known to cause cancer or reproductive toxicity

No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10.

(Added by Initiative Measure, Nov. 4, 1986, eff. Jan. 1, 1987.)

Historical and Statutory Notes

Purpose and effective date of Initiative Measure, Nov. 4, 1986, see Historical and Statutory Notes under § 25249.5.

Amendment of this section by Stats.1990, c. 407 (Prop. 141) was rejected at the Nov. 6, 1990, general election.

Law Review Commentaries

Problems with Prop. 65: Will California's toxics initiative hold water? James Dragna, 10 L.A.Law. 18 (April 1987).

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1. Preemption

The Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C.A. § 136v] did not preempt this section to extent that it merely imposed restrictions on pesticide sale or use, without requiring additions to or deletions from pesticide package labels; many warning methods, including point-of-sale signs currently designated "safe harbor" under this section, could satisfy requirements of California without infringing on federal supremacy in area of pesticide labeling. D-Con Co., Inc. v. Allenby, N.D.Cal.1989, 728 F.Supp. 605.

Principles of comity would not counsel against Court of Appeal's exercising jurisdiction over petition for mandamus ordering state Occupational Safety and Health Standards Board to include in state plan warning and enforcement provisions of this chapter, although manufacturers' association had sought federal declaratory and injunctive relief that this chapter was preempted in the workplace by federal Occupational Safety and Health Act (OSHA) [29 U.S.C.A. § 651 et seq.] because federal hazard communication standard requires employers to warn employees of potential exposure to certain hazardous materials in workplace and state act related to same occupational safety and health issue. California Labor Federation, AFL-CIO v. California Occupational Safety and Health Standards Bd. (App. 1 Dist.1990) 271 Cal.Rptr. 310, 221 Cal.App.3d 1547, review denied.

2. Occupational safety and health plan

Court of Appeal had power to entertain mandamus petition by labor and environmental

No. 96-705

Supreme Court, U.S.
FILED
APR 16 1996
CLERK

IN THE
Supreme Court of the United States
OCTOBER TERM, 1996

COMMITTEE OF DENTAL AMALGAM ALLOY MANUFACTURERS AND DISTRIBUTORS AND DENTSPLY INTERNATIONAL INC.,

Petitioners,

v.

RICHARD A. BECKER, DIRECTOR OF THE OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT, DANIEL E. LUNGREN, ATTORNEY GENERAL OF THE STATE OF CALIFORNIA, AND ENVIRONMENTAL LAW FOUNDATION,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

PETITIONERS' REPLY BRIEF IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

Of Counsel:
THOMAS F. FISE
AMERICAN DENTAL TRADE ASSOCIATION
4900 B. South 31st Street
Arlington, Va. 22206-1656

STANLEY W. LANDFAIR
DANIEL G. JARCHO*
MCKENNA & CUNEO, L.L.P.
1900 K Street, N.W.
Washington, D.C. 20006
(202) 496-7500

Counsel for Petitioners

**Counsel of Record*

PRESS OF BYRON S. ADAMS ✦ WASHINGTON, D.C. ✦ 1-800-347-8208

RULE 29.6 STATEMENT

Petitioners' Rule 29.6 statements filed with the petition for writ of certiorari are accurate and need not be amended to make them current.

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OTHER AUTHORITIES

Brief amicus curiae of the State of California in support of respondents/cross-petitioners Lora Lohr and Michael Lohr, *Medtronic, Inc. v. Lohr*, No. 95-754 (filed Mar. 12, 1996) 5

The critical issues before the Court are whether the Ninth Circuit's conflict in principle with numerous other circuits regarding preemption standards under the Federal Food, Drug, and Cosmetic Act ("FDCA") and the national significance of this case justify Supreme Court review. Instead of focusing on these issues, the state respondents primarily argue the merits of their case. Their approach effectively concedes many of the arguments in the petition.

Stripped of its rhetoric, respondents' analysis *confirms* that there is a substantial conflict in principle among the circuits regarding the scope of preemption under the FDCA: the Ninth Circuit's decision conflicts with the decisions of seven other circuits regarding the types of state requirements that are subject to preemption and also conflicts with four other circuits' decisions regarding the types of federal requirements that have preemptive effect. Although respondents repeatedly assert that *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240 (1996), resolves the conflict, they do not explain how, and they do not even *respond* to petitioners' compelling arguments to the contrary. Furthermore, respondents never deny that the conflict in principle has resulted in great differences from circuit to circuit in the scope of state regulatory power over medical devices, disrupting the device industry to the detriment of the consuming public.

Respondents also ignore or sidestep petitioners' arguments that this case has national significance. They do not contest that the Ninth Circuit has eviscerated the FDCA preemption provision, virtually eliminating preemption of medical device regulation by the nation's most populous State. And they also never deny that if the Ninth Circuit's ruling is allowed to stand, the FDA's decision to assign a medical device to Class I (thereby permitting its manufacture and marketing subject to the lowest level of federal statutory controls), and to reject direct consumer warnings in favor of other warnings to prescribers of the device, would have no

legal significance for any state government. Instead, state governments would be allowed to impose any requirements they like under statutes like Proposition 65, even if they conflicted directly with federal law, and even if they involved ad hoc "bounty hunter" actions by private parties.

Because respondents have not refuted petitioners' substantial arguments favoring Supreme Court review in this case, the Court should grant the petition.[1]

ARGUMENT

I. THE COURT OF APPEALS DECISION ESTABLISHES PREEMPTION STANDARDS THAT CONFLICT WITH THE STANDARDS IN OTHER CIRCUITS

The petition makes clear that the Ninth Circuit's decision confirms a substantial conflict in principle among the circuits concerning the scope of federal preemption under the FDCA. There is a conflict in principle with seven other circuits regarding the types of state requirements that are subject to preemption, and a conflict in principle with four other circuits regarding the types of federal requirements that have preemptive effect. Petition for writ of certiorari ("Pet.") at 13. Respondents argue that the decision below cannot conflict with any of these cases from other circuits, because they (1) involve state common law requirements rather than state statutes; (2) involve different federal requirements than the present case; and (3) predate *Lohr*. Respondents' brief in opposition to petition for writ of certiorari ("Opp.") at 20-26. This Court should reject respondents' analysis and conclude that there is a conflict in principle that justifies review.

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[1] Respondent Environmental Law Foundation did not file a brief in opposition to the petition.

A. A Conflict in Principle with Product Liability Cases from Other Circuits Justifies Review

Respondents first assert that there is no *direct* conflict with the product liability decisions in other circuits identified by petitioners, because the present case involves a state *statute*. Opp. at 23-24. This argument merely restates the obvious point, noted by petitioners (see Pet. at 13), that this case involves a "conflict in principle" rather than a "direct conflict" between holdings. Respondents do not dispute that the Ninth Circuit's test for identifying preempted state requirements is wholly inconsistent with the tests adopted by seven other circuits, see Pet. at 13-15, or explain why this conflict in principle might be an insufficient basis for Supreme Court review.

Indeed, respondents completely fail to confront a critical reason why this conflict in principle is particularly significant—it *derives from, and entrenches*, a substantial "direct conflict" created by earlier Ninth Circuit decisions that *did* involve product liability cases. See Pet. at 15-18, 20-21. Respondents explicitly acknowledge this direct conflict involving Ninth Circuit law, see Opp. at 24, and they do not deny that the court below applied the same Ninth Circuit standards, or that the Ninth Circuit's standards conflict with those adopted by other circuits.[2] Respondents also never contest that these conflicting preemption standards have cre-

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[2] Respondents suggest that the present case is not a proper vehicle for Supreme Court review of these preemption standards, because the "direct conflict" was created by an earlier Ninth Circuit case that this Court declined to review. See Opp. at 22 & n.10 (discussing *Kennedy* v. *Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995), cert. denied, 116 S. Ct. 2579 (1996)). This argument does not withstand scrutiny. Because this Court frequently allows a conflict to "percolate" for some period of time to allow the lower courts' positions to mature, it may not grant certiorari in the very first case that establishes the conflict.

ated a confusing and disjointed pattern of regulatory requirements that disrupt the rational and efficient development, production and sale of critical medical products (see Pet. at 21-22). Given the dramatic differences among the circuits concerning the scope of state regulatory power over medical devices, this Court should decide, as it has on many occasions in the past, that a conflict in principle is sufficient basis for granting review.

The Court also should reject respondents' assertion that "any conflicts concerning preemption of particular common law claims can only be resolved in the context of cases raising the same or similar common law claims." Opp. at 25. To the contrary, this case is an ideal vehicle to resolve the conflict regarding the standards for identifying state requirements that are subject to preemption.

Respondents ignore the fact that five Justices of this Court have explicitly confirmed that preemption analysis under the FDCA does *not* depend on the source of state law, and that the FDCA preemption provision treats state requirements the same regardless of whether they derive from statutes or common law doctrines. See Pet. at 14 n.7.[3] In addition, respondents' own analysis confirms that the source of state law is irrelevant to the preemption analysis. Their merits arguments are fundamentally assertions that this

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[3] Justice O'Connor's opinion in *Lohr*, which garnered four votes, made clear that the FDCA preemption provision "clearly pre-empts any state common-law action that would impose a requirement different from, or in addition to, that applicable under the FDCA—*just as it would pre-empt a state statute or regulation that had that effect.*" 116 S. Ct. at 2263 (emphasis added). In a separate opinion, Justice Breyer agreed that "ordinarily, insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, *it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action.*" *Id.* at 2260 (emphasis added).

Court's analysis in a *product liability* case (i.e., *Lohr*) required the result reached by the court below in a case involving a *state statute*. Thus, the opposition brief asserts repeatedly that the Ninth Circuit decision was "based directly on" *Lohr* (Opp. at 3), "closely tracked both the reasoning and holdings" of *Lohr* (*id.* at 12, 28), "addresses the same statute and regulations that were at issue" in *Lohr* (*id.* at 2), and "is absolutely consistent with this Court's opinion" in *Lohr* (*ibid.*).[4] These arguments concede that the source of state law does not change preemption analysis and confirm that the present case is a proper vehicle for resolving the conflict in principle with product liability cases from other circuits.

B. Review Is Justified by a Conflict in Principle with Cases from Other Circuits Involving Different Federal Requirements

This Court also should reject respondents' argument that there can be no conflict between the present case and the other cases identified in the petition, because the other circuits' cases involve federal requirements other than the prescription device labeling regulation, 21 C.F.R. 801.109. Opp. at 22. In advancing this argument, respondents once again imply that Supreme Court review is not appropriate without a "direct conflict" between cases interpreting the same requirement. *Id.* at 21. Yet respondents do not even refer to the Ninth Circuit's conflict in principle with four

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[4] Respondents further underscored the applicability of product liability decisions in the present case by filing an *amicus curiae* brief in *Lohr*. See Opp. at 3 n.1. The brief is exclusively devoted to a discussion of the potential impact a decision in *Lohr* would have in the present case. The brief predicted accurately that "while this [*Lohr*] Court is faced with the preemption of common law claims, its rulings may equally affect state statutory enactments like Proposition 65." Brief amicus curiae of the State of California in support of respondents/cross-petitioners Lora Lohr and Michael Lohr at 10-11, *Medtronic, Inc. v. Lohr*, No. 95-754 (filed Mar. 12, 1996).

other circuits, created by completely inconsistent tests for preemptive federal requirements.[5] See Pet. at 18-19. As the discussion above indicates, the conflict in principle explained in the petition should compel this Court to grant review.

C. *Medtronic, Inc.* v. *Lohr* Did Not Resolve the Conflict in Principle Regarding the Scope of FDCA Preemption

This Court also should reject respondents' assertion that "any conflicts exist only with cases that predate [*Lohr*] and are therefore no longer necessarily good law," and that "there is no conflict" because "no other circuit court has had the opportunity to apply" guidance from *Lohr*. Opp. at 20.

First, this Court should reject respondents' assertion that there is no conflict among the circuits regarding preemptive federal requirements, because this case is the only post-*Lohr* decision to address the preemptive scope of the prescription device labeling regulation. Opp. at 21. Respondents' argument is based on the erroneous premise that pre-*Lohr* cases regarding preemptive federal requirements are no longer good law. See Opp. at 20. Respondents give absolutely no explanation *why* the decisions from four other circuits cited in the petition are no longer good law, and respondents do not even address the reasons, advanced by petitioners, that those decisions are still valid following *Lohr*. See Pet. at 20-21. Instead, respondents argue that two *other* circuit cases *not* cited in the petition are no longer good law, because they conflict with *Lohr*. Opp. at 21 n.8. Yet the conflict in principle identified in the petition does not involve these other

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[5] Respondents and petitioners disagree about the scope of the test for preemptive federal requirements adopted by the court below. Compare Pet. at 18-19 with Opp. at 14. However, respondents never even suggest that their interpretation of the Ninth Circuit's test resolves the conflict with the tests adopted by the other circuits.

cases; respondents' argument therefore does not withstand scrutiny.[6]

Second, this Court should reject respondents' argument that there is no conflict regarding the test for preempted state requirements following *Lohr*. See Opp. at 20. Respondents suggest erroneously that pre-*Lohr* decisions regarding state law requirements are no longer good law. *Id.* Respondents' arguments ignore the fact that *Lohr* supports the continued validity of cases from seven circuits establishing the conflict in principle, because five Justices confirmed that "generally applicable" common law requirements are subject to preemption under the FDCA. See Pet. at 15-16. Instead of addressing the opinions of these Justices, respondents rely exclusively on passages from Justice Stevens' opinion, which they assert should foreclose preemption of generally applicable state requirements. See Opp. at 15, 24. In so doing, respondents merely confirm that the different *Lohr* opinions lack consistency on some issues (see Pet. at 15-16 & n.10)—respondents do *not* establish that the cases cited by petitioners are bad law. Indeed, given the inconsistencies in *Lohr*, this Court should review this case to clarify these issues in the best interests of the device industry and the consuming public.

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[6] In their argument on the merits, respondents also suggest incorrectly that *Lohr* resolved the question of preemption in this case by holding that the prescription device labeling regulation did not preempt state law requirements. See Opp. at 14. This argument overlooks the fact that the *Lohr* holding was limited to the particular common law claims at issue in that case; this Court made clear that in other cases, an individualized comparison between other particular state and federal requirements will be necessary to make a ruling on the merits of the preemption issue. See Pet. at 20 & n.15. Respondents also completely ignore the fact that there are federal requirements other than the prescription device labeling regulation that could preempt the Proposition 65 warnings in this case. See *id.* at 6-8.

II. THIS CASE PRESENTS AN IMPORTANT FEDERAL QUESTION THAT HAS NOT BEEN, BUT SHOULD BE, SETTLED BY THIS COURT

This case presents the Court with a superb opportunity to define for the first time the critical balance of state and federal regulatory power over medical devices. In particular, a decision in this case would address the scope of state regulatory power when the FDA regulates by assigning a device to Class I (because more stringent controls are unnecessary to provide reasonable assurance of safety and effectiveness)[7] and deliberately declines to impose additional requirements in formal agency proceedings. Respondents' only reply is a simplistic observation that the FDA has the authority to preempt state regulatory power if it so desires. See Opp. at 26. But this response begs the question, which is whether the Agency's regulatory decision described above—albeit a passive one—has preemptive effect.[8]

Moreover, respondents' argument does not detract from the significance of the case, which itself justifies Supreme Court review. See Pet. at 23-24. The Ninth Circuit's test for

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[7] See Pet. at 4.

[8] In one of their arguments on the merits, respondents assert that agency inaction cannot preempt state law, because the FDCA requires a federal "requirement" for preemption to occur, and inaction does not yield a requirement. See Opp. at 16-20. This argument misses the point. Petitioners agree that there can be no preemption without an applicable federal requirement. If review is granted, petitioners will argue that the Proposition 65 warnings are preempted, because they are "different from, or in addition to," extensive federal requirements that *do* apply to dental mercury, when those requirements are considered in conjunction with the FDA's affirmative rejection of additional reproductive toxicity warnings. See Pet. at 6-8 (describing federal requirements), 20 n.15 (describing preemptive effect of federal requirements in context of FDA's rejection of reproductive toxicity warnings).

preemption will virtually *never* invalidate state law. See Pet. at 2. If the Ninth Circuit's decision is allowed to stand, then the States of that circuit will be permitted to impose virtually any requirement they desire on FDA-regulated medical devices, even if the state requirement directly conflicts with federal law. See Pet. at 26.

Furthermore, this case is an appropriate vehicle to review the important federalism issues at stake, because the assertion of regulatory power by the State of California under the Proposition 65 "bounty hunter" clause is particularly extensive, affecting the ability of numerous national manufacturing companies to distribute products through interstate commerce into the nation's largest market. See Pet. at 25-26. Respondents do not refute this fact, arguing only that the "bounty hunter" provisions of this state statute are also present in federal statutes not relevant to this case. See Opp. at 9, 27. Respondents do not even respond to the argument that this extraordinarily broad assertion of state power provides an excellent context for review of the issues presented. Nor do they address the national controversy that is raging from the attempts by "bounty hunters" to apply Proposition 65 requirements that conflict with federal law.[9]

Finally, respondents say little to address petitioners' argument that this case is worthy of Supreme Court review, because Proposition 65 may require warnings that violate federal law. See Pet. at 26. Although respondents make

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[9] The petition noted that the national significance of the preemption issue is confirmed by pending OSHA proceedings considering preemption of Proposition 65 warnings. See Pet. at 26 n.17. In the short time since the petition was filed, over 150 manufacturing companies and ten national trade associations (representing thousands of national manufacturers) have filed comments in those OSHA proceedings, confirming that Proposition 65 "bounty hunter" suits are having a significant impact on companies that do business in all fifty States.

various claims to discount the significance of the federal government report that petitioners cite for this proposition (see Opp. at 27-28), they never deny that the FDA's parent agency, the Department of Health and Human Services, issued this formal report, authored in part by FDA personnel, stating that federal law *prohibits* the types of warnings that are currently being *required* under state law through Proposition 65 "bounty hunter" suits. See Pet. at 26. They also never deny the underlying logic of petitioners' argument: if the FDA determines that there is no legitimate scientific basis for reproductive toxicity warnings, the general controls provisions of the FDCA barring misleading labeling would prevent manufacturers from adding the warnings. See Pet. at 8 (citing 21 U.S.C. 352(a), 321(n)). This direct clash between state and federal requirements justifies Supreme Court review of this case.

CONCLUSION

This Court should grant the petition for certiorari.

Respectfully submitted,

Of Counsel
THOMAS F. FISE
AMERICAN DENTAL TRADE ASSOCIATION
4900 B. South 31st Street
Arlington, Virginia 22206-1656

STANLEY W. LANDFAIR
DANIEL G. JARCHO*
MCKENNA & CUNEO, L.L.P.
1900 K Street, N.W.
Washington, D.C. 20006
(202) 496-7500

Counsel for Petitioners

**Counsel of Record*

December 16, 1996

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No. 96-705

IN THE
SUPREME COURT OF THE UNITED STATES
OCTOBER TERM, 1996

COMMITTEE OF DENTAL AMALGAM ALLOY MANUFACTURERS AND DISTRIBUTORS AND DENTSPLY INTERNATIONAL INC.,
Petitioners,
v.
RICHARD A. BECKER, DIRECTOR OF THE OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT, DANIEL E. LUNGREN, ATTORNEY GENERAL OF THE STATE OF CALIFORNIA, AND ENVIRONMENTAL LAW FOUNDATION,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

PETITIONERS' REPLY IN SUPPORT OF MOTION TO FILE RULE 29.6 STATEMENT UNDER SEAL

Of Counsel
THOMAS F. FISE
AMERICAN DENTAL TRADE ASSOCIATION
4900 B. South 31st Street
Arlington, Virginia
22206-1656

STANLEY W. LANDFAIR
DANIEL G. JARCHO*
McKENNA & CUNEO, L.L.P.
1900 K Street, N.W.
Washington, D.C. 20006
(202) 496-7500
Counsel for Petitioners
**Counsel of Record*

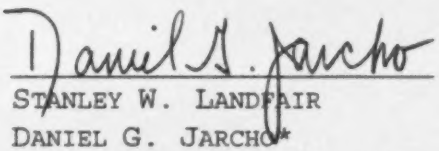
3pp

PETITIONERS' REPLY IN SUPPORT
OF MOTION TO FILE RULE 29.6 STATEMENT UNDER SEAL

Petitioners respectfully submit this reply in support of their motion to accept the filing of a portion of their Rule 29.6 Statement under seal, because the information it contains is currently restricted from disclosure under a protective order entered by the district court in this action.

In its opposition to the motion, respondent Environmental Law Foundation suggested that the motion should be denied, because the identities of the companies comprising petitioner Committee of Dental Amalgam Alloy Manufacturers and Distributors all have been disclosed previously through discovery. This assertion is refuted by a comparison of the list of companies set forth in the Rule 29.6 statement filed under seal with the list of companies provided by respondent Environmental Law Foundation in its opposition.

Respectfully submitted,



STANLEY W. LANDFAIR
DANIEL G. JARCHO*
McKENNA & CUNEO, L.L.P.
1900 K Street, N.W.
Washington, D.C. 20006
(202) 496-7500

Counsel for Petitioners

**Counsel of Record*

Of Counsel
THOMAS F. FISE
AMERICAN DENTAL TRADE ASSOCIATION
4900 B. South 31st Street
Arlington, Virginia
22206-1656

CERTIFICATE OF SERVICE

I hereby certify that on November 26, 1996, a true and correct copy of the foregoing Petitioners' Reply in Support of Motion to File Rule 29.6 Statement Under Seal was served on counsel for Respondents by U.S. first-class mail, postage prepaid:

Susan S. Fiering, Esq.
Deputy Attorney General
State of California
Department of Justice
2101 Webster Street, 12th Floor
Oakland, California 94612
(510) 286-3892
Counsel for Respondents Richard A. Becker and Daniel E. Lungren

James Wheaton, Esq.
President
Environmental Law Foundation
1736 Franklin Street, 8th Floor
Oakland, California 94612
(510) 208-4555
Counsel for Respondent Environmental Law Foundation

Daniel G. Jarcho